

US3762177 (Prod: Wake Forest University Health Sciences)

Generated By: KC Joubran

Generated On: 26 Nov 2020 11:15:26

All time stamps listed in this document are displayed in GMT

US3762177

Form: Participant Creation

Generated On: 26 Nov 2020 11:15:26

[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 11:15:26

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	03 SEP 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 11:15:26

Date of Birth (MMM yyyy)	(b) (6) 1954
Age	65
Age Units	YEARS
Age (Derived)	66
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 11:15:26

Date of Informed Consent (<i>dd MMM yyyy</i>)	3 SEP 2020
Month and Year of Informed Consent (derived)	SEP 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 11:15:26

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:15:26

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:15:26

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	01 UNK 1983
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 1983
Start Year (derived)	1983
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:15:26

Condition	DEPRESSION
Start date (dd MMM yyyy)	01 UNK 1998
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 1998
Start Year (derived)	1998
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:15:26

Condition	URINARY INCONTINENCE
Start date (dd MMM yyyy)	01 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 (4)

Generated On: 26 Nov 2020 11:15:26

Condition	POST MENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:15:26

Condition	FREQUENT CONSTIPATION
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:15:26

Condition	HEPATITIS A
Start date (dd MMM yyyy)	UN UNK 1959
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1959
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1959
Start Year (derived)	1959
Stop Month and Year (derived)	JAN 1959
Stop Year (derived)	1959

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:15:26

Condition	IRRITABLE BOWEL SYNDROME
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:15:26

Condition	DIVERTICULITIS
Start date (dd MMM yyyy)	UN UNK 2002
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 2002
Start Year (derived)	2002
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:15:26

Condition	NECK PAIN
Start date (dd MMM yyyy)	UN UNK 1969
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 1969
Start Year (derived)	1969
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:15:26

Condition	OSTEOARTHRITIS
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:15:26

Condition	OSTEOPENIA
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:15:26

Condition	LOWER BACK PAIN
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 (13)

Generated On: 26 Nov 2020 11:15:26

Condition	CARPAL TUNNEL SYNDROME
Start date (dd MMM yyyy)	UN UNK 2002
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 2002
Start Year (derived)	2002
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:26

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	03 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	13:26 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 13:26
Height (<i>xxx.x</i>)	63 in
Weight (<i>xxx.x</i>)	142 lb
BMI (<i>xxx.x</i>)	25.20677 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 11:15:26

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

03 SEP 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 11:15:26

Date of assessment (<i>dd MMM yyyy</i>)	03 SEP 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>) _____	
Date of surgery unknown	False
If Post-menopausal, date of last menstruation (<i>dd MMM yyyy</i>)	UN UNK 2000
Date of last menstruation unknown	False

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:26

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

Resides in Nursing Home or Assisted Living Facility False

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

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Folder: Screening

Form: Risk of Exposure

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Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:15:26

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	03 SEP 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 11:15:26

What was the date of randomization? (dd MMM yyyy) 03 SEP 2020

What was the participant's randomization number? 189875

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 11:15:26

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 11:15:26

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)	03 SEP 2020
Time of assessment (00:00-23:59)	13:26 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 13:26
Temperature (xxx.x)	97.0 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 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 11:15:26

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)	03 SEP 2020
Time of assessment (00:00-23:59)	14:57 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 14:57
Temperature (xxx.x)	97.7 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:26

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 11:15:26

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)	3 SEP 2020
What was the treatment time? (00:00-23:59)	14:19 (24 HR)
Treatment Date and Time (derived)	3 SEP 2020 14:19
Which arm was used to give treatment?	Left Arm ☐
	Right Arm ☒
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:26

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

03 SEP 2020

Collection time (*00:00-23:59*)

13:40 (24 HR)

Collection date and time (derived)

03 SEP 2020 13:40

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:15:26

Collection date (<i>dd MMM yyyy</i>)			03 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:44	03 SEP 2020 13:44
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:15:26

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 11:15:26

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

03 SEP 2020 14:50

PC Open Date & Time

03 SEP 2020 14:39

PC Close Date & Time

03 SEP 2020 17:09

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:15:26

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 97.3 °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	03 SEP 2020 21:48
PC Open Date & Time	03 SEP 2020 18:04
PC Close Date & Time	04 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

04 SEP 2020 18:49

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:15:26

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	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):

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	05 SEP 2020 21:05
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:15:26

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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 19:52

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes ☒
	No ☐
Please record your TEMPERATURE in °F	97.9 °F
Was any MEDICATION TAKEN today for pain or fever ?	Yes ☒
	No ☐

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	07 SEP 2020 20:22
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

08 SEP 2020 21:28

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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

09 SEP 2020 20:50

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:15:26

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

03 SEP 2020 14:51

PC Open Date & Time

03 SEP 2020 14:39

PC Close Date & Time

03 SEP 2020 17:09

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:26

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 ☐

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

20

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

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

Yes ☒

No ☐

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

4

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

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

Please select one response below

None ☒

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

03 SEP 2020 21:54

PC Open Date & Time

03 SEP 2020 18:04

PC Close Date & Time

04 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:26

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 ☐

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

65

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

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

Yes ☒

No ☐

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

30

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 18:53

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

95

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

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

Yes ☒

No ☐

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

30

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 21:06

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:15:26

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 ☐

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

110

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

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

Yes ☒

No ☐

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

30

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 SEP 2020 19:52

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

80

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

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

Yes ☒

No ☐

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

20

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 SEP 2020 20:23

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:15:26

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 ☐

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

80

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

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

Yes ☒

No ☐

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

20

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 21:29

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

60

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

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

Yes ☐

No ☒

Please record - **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

09 SEP 2020 20:51

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:26

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

No ☒

Yes ☐

PC Time stamp	03 SEP 2020 14:52
PC Open Date & Time	03 SEP 2020 14:39
PC Close Date & Time	03 SEP 2020 17:09

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:26

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

No ☒

Yes ☐

PC Time stamp	03 SEP 2020 21:55
PC Open Date & Time	03 SEP 2020 18:04
PC Close Date & Time	04 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:26

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 ☒

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:26

Yes ☐	
PC Time stamp	04 SEP 2020 18:54
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:26

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 ☒

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:26

Yes ☐	
PC Time stamp	05 SEP 2020 21:07
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:26

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 ☒

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:26

Yes ☐	
PC Time stamp	06 SEP 2020 19:53
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:26

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 ☒

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:26

Yes ☐	
PC Time stamp	07 SEP 2020 20:24
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:26

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 ☒

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:26

Yes ☐	
PC Time stamp	08 SEP 2020 21:30
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:26

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 ☒

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:26

Yes ☐	
PC Time stamp	09 SEP 2020 20:51
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(8)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

DAY 8

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

40

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

PC Time Stamp

11 SEP 2020 07:46

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(9)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

DAY 9

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

110

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

PC Time Stamp

11 SEP 2020 20:07

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(10)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

DAY 10

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

110

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

PC Time Stamp

12 SEP 2020 19:52

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(11)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

DAY 11

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

150

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

PC Time Stamp

13 SEP 2020 18:24

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(12)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

DAY 12

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

140

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

PC Time Stamp

14 SEP 2020 22:13

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(13)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

DAY 13

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

100

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

PC Time Stamp

15 SEP 2020 21:25

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(14)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

DAY 14

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

130

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

PC Time Stamp

16 SEP 2020 20:43

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(15)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

DAY 15

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

130

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

PC Time Stamp

17 SEP 2020 12:12

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(16)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

DAY 16

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

130

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

PC Time Stamp

18 SEP 2020 20:27

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(17)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

DAY 17

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

95

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

PC Time Stamp

19 SEP 2020 20:32

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(18)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

DAY 18

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

95

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

PC Time Stamp

21 SEP 2020 07:22

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(19)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

DAY 19

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

90

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

PC Time Stamp

22 SEP 2020 00:24

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(20)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

DAY 20

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

95

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

PC Time Stamp

23 SEP 2020 02:14

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(21)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

DAY 21

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

80

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

PC Time Stamp

23 SEP 2020 23:43

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(22)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

DAY 22

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

80

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

PC Time Stamp

24 SEP 2020 18:23

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(23)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

DAY 23

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

70

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

PC Time Stamp

25 SEP 2020 13:42

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(24)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

DAY 24

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

70

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

PC Time Stamp

26 SEP 2020 23:02

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(25)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

DAY 25

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

75

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

PC Time Stamp

27 SEP 2020 23:24

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(26)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

DAY 26

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

70

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

PC Time Stamp

28 SEP 2020 21:53

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(27)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

DAY 27

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

70

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

PC Time Stamp

29 SEP 2020 12:13

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(28)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

DAY 28

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

70

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

PC Time Stamp

30 SEP 2020 22:43

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(29)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

DAY 29

Is there any REDNESS AT INJECTION SITE?

Yes ☐

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

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

PC Time Stamp

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(30)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

DAY 30

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

80

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

PC Time Stamp

02 OCT 2020 20:42

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(31)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

DAY 31

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

80

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

PC Time Stamp

03 OCT 2020 21:22

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(32)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

DAY 32

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

70

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

PC Time Stamp 05 OCT 2020 08:59

PC Open Date & Time 04 OCT 2020 12:00

PC Close Date & Time 05 OCT 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(33)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

DAY 33

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

70

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

PC Time Stamp 05 OCT 2020 14:19

PC Open Date & Time 05 OCT 2020 12:00

PC Close Date & Time 06 OCT 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(34)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

DAY 34

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

70

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

PC Time Stamp

06 OCT 2020 19:32

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(35)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

DAY 35

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

70

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

PC Time Stamp

07 OCT 2020 19:22

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(36)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

DAY 36

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

50

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

PC Time Stamp

09 OCT 2020 00:40

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(37)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

DAY 37

Is there any REDNESS AT INJECTION SITE?

Yes ☒

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

40

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

PC Time Stamp 09 OCT 2020 22:52

PC Open Date & Time 09 OCT 2020 12:00

PC Close Date & Time 10 OCT 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(38)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

DAY 38

Is there any REDNESS AT INJECTION SITE?

Yes ☐

No ☒

PC Time Stamp

11 OCT 2020 07:18

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	11 SEP 2020 07:46
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	11 SEP 2020 20:07
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	12 SEP 2020 19:52
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT	DAY 11
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	13 SEP 2020 18:24
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT	DAY 12
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	14 SEP 2020 22:13
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

DAY 13

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

No ☒

Yes ☐

PC Time stamp

15 SEP 2020 21:26

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT	DAY 14
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	16 SEP 2020 20:43
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

DAY 15

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

No ☒

Yes ☐

PC Time stamp

17 SEP 2020 12:12

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT	DAY 16
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☐ Yes ☒
PC Time stamp	18 SEP 2020 20:27
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT	DAY 17
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	19 SEP 2020 20:33
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT	DAY 18
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	21 SEP 2020 07:22
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

DAY 19

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

No ☒

Yes ☐

PC Time stamp

22 SEP 2020 00:24

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT	DAY 20
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	23 SEP 2020 02:14
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT	DAY 21
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	23 SEP 2020 23:43
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT	DAY 22
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	24 SEP 2020 18:23
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

DAY 23

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

No ☒

Yes ☐

PC Time stamp

25 SEP 2020 13:42

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT	DAY 24
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	26 SEP 2020 23:02
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT	DAY 25
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	27 SEP 2020 23:24
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT	DAY 26
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	28 SEP 2020 21:53
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT	DAY 27
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	29 SEP 2020 12:13
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(28)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT	DAY 28
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	30 SEP 2020 22:43
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

DAY 29

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(30)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT	DAY 30
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	02 OCT 2020 20:42
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(31)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT	DAY 31
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	03 OCT 2020 21:22
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(32)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT	DAY 32
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	05 OCT 2020 08:59
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(33)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

DAY 33

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

No ☒

Yes ☐

PC Time stamp

05 OCT 2020 14:19

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(34)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

DAY 34

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

No ☒

Yes ☐

PC Time stamp

06 OCT 2020 19:32

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(35)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

DAY 35

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

No ☒

Yes ☐

PC Time stamp

07 OCT 2020 19:23

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(36)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT	DAY 36
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	09 OCT 2020 00:40
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(37)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT	DAY 37
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	09 OCT 2020 22:53
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(38)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT	DAY 38
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	11 OCT 2020 07:18
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3762177

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:26

Was Contact Attempted?

Yes ☒

No ☐

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

10 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3762177

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762177

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3762177

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762177

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:26

Was Contact Attempted?

Yes ☒

No ☐

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

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3762177

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762177

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:26

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	01 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:26

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	01 OCT 2020
Time of assessment (00:00-23:59)	13:34 (24 HR)
Vital Signs Date and Time (derived)	01 OCT 2020 13:34
Temperature (xxx.x)	97.8 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:26

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	

US3762177

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:26

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 OCT 2020

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

US3762177

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:26

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 SEVERE REACTION AFTER FIRST VACCINATION.

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? _____

US3762177

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:26

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

01 OCT 2020

Collection time (*00:00-23:59*)

14:00 (24 HR)

Collection date and time (derived)

01 OCT 2020 14:00

US3762177

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:15:26

Collection date (dd MMM yyyy)			01 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:01	01 OCT 2020 14:01
Nasopharyngeal Swab 2	No		

US3762177

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762177

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3762177

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762177

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:26

Was Contact Attempted?

Yes ☒

No ☐

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

15 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3762177

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762177

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3762177

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762177

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:26

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	05 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3762177

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:26

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	05 NOV 2020
Time of assessment (<i>00:00-23:59</i>)	12:32 (24 HR)
Vital Signs Date and Time (derived)	05 NOV 2020 12:32
Temperature (<i>xxx.x</i>)	98.0 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	72 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3762177

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:26

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.

US3762177

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:26

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

05 NOV 2020

Collection time (*00:00-23:59*)

12:36 (24 HR)

Collection date and time (derived)

05 NOV 2020 12:36

US3762177

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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	03 NOV 2020 00:05:08
Patient Cloud Open Date & Time	03 NOV 2020 00:01
Patient Cloud Close Date & Time	07 NOV 2020 23:59

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

12 NOV 2020 08:32:43

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	False
Chills	False
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	False
Body aches	True
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	True
Runny nose	True
Nausea	False
Vomiting	True
Diarrhea	True
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☒
Have 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	17 NOV 2020 11:46:43
Patient Cloud Open Date & Time	17 NOV 2020 00:01
Patient Cloud Close Date & Time	21 NOV 2020 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 NOV 2020 12:19:54
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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26 DEC 2020 00:01

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30 DEC 2020 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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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06 JAN 2021 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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 JAN 2021 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

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20 JAN 2021 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

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27 JAN 2021 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

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10 FEB 2021 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

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24 FEB 2021 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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°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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

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27 APR 2022 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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°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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

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01 JUN 2022 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

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08 JUN 2022 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

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06 JUL 2022 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

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13 JUL 2022 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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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US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

Date and time of submission

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23 JUL 2022 00:01

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27 JUL 2022 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

Date and time of submission

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30 JUL 2022 00:01

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03 AUG 2022 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

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10 AUG 2022 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

Date and time of submission

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13 AUG 2022 00:01

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17 AUG 2022 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2022 00:01

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24 AUG 2022 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

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07 SEP 2022 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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°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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 ☐

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2022 23:59

US3762177

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:26

Was Contact Attempted?

Yes ☐

No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3762177

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:26

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:15:26

Date of Contact	18 SEP 2020
Time of Contact	10:00
Date and Time of Contact (derived)	18 SEP 2020 10:00
Type of Contact	Clinic Visit - Scheduled ☐
	Clinical Visit - Unscheduled ☒
	Safety Call ☐
	Convalescent Tele-visit ☐
Has the subject reported symptoms of SARS-COV-2?	Yes ☒
	No ☐

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:26

Symptom Day

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

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:26

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	19 SEP 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	97.7 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	372 of 2244	

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:26

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

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:26

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:26

Symptom Day

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

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:26

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	20 SEP 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	96.5 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	376 of 2244	

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:26

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

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:26

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:26

Symptom Day

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

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:26

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	21 SEP 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	380 of 2244	

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:26

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

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:26

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:15:26

Date of Visit	18 SEP 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes ☒ No ☐
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes ☐ No ☒
Date of Test	18 SEP 2020
Type of Test Performed	Nasopharyngeal Swab ☒ Nasal Swab ☐ Saliva Test ☐ Other ☐
Other, specify _____	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes ☐ No ☒
If yes, provide lab information below	
Lab/ Institution Test Performed	_____
CLIA Certified?	Yes ☐ No ☐
COVID-19 Positive (CSA Programming Field Only)	0

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 11:15:26

[Generate Next COVID-19 Assessment](#)

Yes ☐
No ☒

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Folder: Illness Visit (1)

Form: Saliva Collection

Generated On: 26 Nov 2020 11:15:26

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	20 SEP 2020
Day 5	NA (COVID-19 Negative)	
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3762177

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:26

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	18 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SICKD1

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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:26

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	18 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	10:00 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 10:00
Height (<i>xxx.x</i>)	63 in
Weight (<i>xxx.x</i>)	145 lb
Temperature (<i>xxx.x</i>)	97.8 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	70 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	68 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3762177

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:26

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 SEP 2020

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

US3762177

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 11:15:26

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

18 SEP 2020

US3762177

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:26

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

Was visit performed at the participant's home or at the clinic? Home ☐
Clinic ☐

Folder OID _____

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Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:26

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)	

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Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:26

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.

US3762177

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 11:15:26

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

Yes ☐

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

US3762177

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:15:26

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3762177

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:26

AEID	
Adverse event	INJECTION SITE REDNESS, LEFT ARM NON-URTICARIAL
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)	00:00 (24 HR)
AE start date and time (derived)	03 SEP 2020 00:00
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:26

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

US3762177

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:26

AEID	
Adverse event	FATIGUE
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)	04 SEP 2020
Start time (00:00-23:59)	00:00 (24 HR)
AE start date and time (derived)	04 SEP 2020 00:00
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:26

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

US3762177

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:26

AEID	
Adverse event	STOMACH ACHE
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)	13 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)	
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

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:26

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

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:26

AEID	
Adverse event	INTERMITTENT BODY ACHES
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)	04 SEP 2020
Start time (00:00-23:59)	00:00 (24 HR)
AE start date and time (derived)	04 SEP 2020 00:00
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:26

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

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:26

AEID	
Adverse event	VOMIT
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)	27 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	27 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
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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:26

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

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:26

PT STATED SHE ATE
LEFTOVERS ON 10/26/2020 AND
HAD VOMITING ON 10/27/2020
AND STOMACH PAIN FROM
10/27/2020 UNTIL VISIT 3 WITH
HER PCP ON 11/2/2020. PCP
PRESCRIBED VENTYL PRN FOR
STOMACH PAINS AND PT TOOK
HER FIRST DOSE 11/3/2020. PCP
INDICATED TO THE PT THAT
THIS MAY BE MORE RELATED
TO HER IBS AND
DIVERTICULITIS THAN COVE
STUDY.

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)	

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:26

AEID	
Adverse event	STOMACH PAINS
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)	27 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
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

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:26

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	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:26

PT STATED SHE ATE
LEFTOVERS ON 10/26/2020 AND
HAD VOMITING ON 10/27/2020
AND STOMACH PAIN FROM
10/27/2020 UNTIL VISIT 3 WITH
HER PCP ON 11/2/2020. PCP
PRESCRIBED VENTYL PRN FOR
STOMACH PAINS AND PT TOOK
HER FIRST DOSE 11/3/2020. PCP
INDICATED TO THE PT THAT
THIS MAY BE MORE RELATED
TO HER IBS AND
DIVERTICULITIS THAN COVE
STUDY.

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:15:26

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

Yes ☒

No ☐

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

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:26

Name of Medication	LEVOTHYROXINE
Prophylaxis	Yes ☐ No ☒
Indication	HYPOTHYROID
Dose per administration	125
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 ☐

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:26

	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)		01 SEP 1983
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	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:26

Name of Medication	LIOTHYRONINE
Prophylaxis	Yes ☐ No ☒
Indication	HYPOTHYROID
Dose per administration	10
Dose unit	mg ☐ ug ☒ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:26

	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 MAY 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	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:26

Name of Medication	WELLBUTRIN
Prophylaxis	Yes ☐ No ☒
Indication	DEPRESSION
Dose per administration	150
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	UNKNOWN
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:26

	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)	01 UNK 2000	
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 ☒	

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:26

Name of Medication	ACETAMINOPHEN
Prophylaxis	Yes ☒ No ☐
Indication	MUSCLE ACHES
Dose per administration	325
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:26

	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 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		05 SEP 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	☒

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:26

Name of Medication	ACETAMINOPHEN
Prophylaxis	Yes ☒ No ☐
Indication	MUSCLE ACHES
Dose per administration	325
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:26

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)	07 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ☒
If not Ongoing, End date (dd MMM yyyy) 07 SEP 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 ☒

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:26

Name of Medication	ACETAMINOPHEN
Prophylaxis	Yes ☐ No ☒
Indication	INTERMITTENT BODY ACHES
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☒ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:26

	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 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		07 SEP 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:26

Name of Medication	OMEPRAZOLE
Prophylaxis	Yes ☐ No ☒
Indication	STOMACH ACHE
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 ☐

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:26

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		13 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)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:26

Name of Medication	IMMODIUM
Prophylaxis	Yes ☐ No ☒
Indication	STOMACH ACHE
Dose per administration	2
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:26

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		13 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)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3762177

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:15:26

Were any concomitant procedures performed?

Yes ☐

No ☐

If yes, please complete Concomitant Procedures form.

US3762177

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:15:26

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3762177

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:15:26

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

US3762177 (Prod: Wake Forest University Health Sciences)

US3762177

Form: Participant Creation

Generated On: 26 Nov 2020 11:15:26

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:42:18
User entered 'US3762177'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 17:34:41

US3762177

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:15:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Samantha Wheeler (b) (4)	03 Sep 2020 18:24:52
	(b) (4)	

US3762177

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered '03 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	03 Sep 2020 17:34:42

US3762177

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Samantha Wheeler (b) (4) (b) (4)	03 Sep 2020 18:24:52

US3762177

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:15:26

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	03 Sep 2020 18:24:52

US3762177

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered (b) (6) 1954'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	03 Sep 2020 17:34:43

US3762177

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:26

Age

Audit	User	Time (GMT)
User closed query 'Per CDM: Please complete the form' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 16:32:23
Query 'Per CDM: Please complete the form' answered with 'Date of birth is (b) (6) 1954. At time of visit patient is 65 years old.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 11:24:24
User entered '65' reason for change: Per Query Resolution	(b) (4), (b) (6)	11 Sep 2020 11:23:41
User entered '66' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 11:22:03
User entered '65'	(b) (4), (b) (6)	11 Sep 2020 11:21:09
User opened query 'Per CDM: Please complete the form' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 07:52:06

US3762177

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:26

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	11 Sep 2020 11:21:09

US3762177

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:26

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '66'	System	03 Sep 2020 18:05:15

US3762177

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:26

[Sex](#)

Audit	User	Time (GMT)
User entered 'Female (F)'	(b) (4), (b) (6)	11 Sep 2020 11:21:09

US3762177

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:26

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4), (b) (6)	11 Sep 2020 11:21:09

US3762177

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:26

[White](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	11 Sep 2020 11:21:09

US3762177

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:26

[Black](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 11:21:09

US3762177

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:26

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 11:21:09

US3762177

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:26

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 11:21:09

US3762177

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:26

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 11:21:09

US3762177

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:26

[Other](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 11:21:09

US3762177

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:26

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 11:21:09

US3762177

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:26

[Unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 11:21:09

US3762177

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:26

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 11:21:09

US3762177

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered '3 Sep 2020'	(b) (4), (b) (6)	03 Sep 2020 18:05:15

US3762177

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered 'Sep 2020'	System	03 Sep 2020 18:05:15

US3762177

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered '2020'	System	03 Sep 2020 18:05:15

US3762177

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:15:26

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 3 (3)'	(b) (4), (b) (6)	03 Sep 2020 18:05:15

US3762177

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 18:05:15

US3762177

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 18:05:15

US3762177

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:15:26

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 18:05:15

US3762177

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:15:26

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 18:05:15

US3762177

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:15:26

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	03 Sep 2020 17:34:42

US3762177

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:15:26

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 18:05:15

US3762177

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 18:05:00

US3762177

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:15:26

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 11:25:00

US3762177

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:15:26

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 11:26:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 11:26:42
Data point term sent to Coder	System	11 Sep 2020 11:25:46
User entered 'Hypothyroidism'	(b) (4), (b) (6)	11 Sep 2020 11:25:37

US3762177

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered '01 UNK 1983'	(b) (4), (b) (6)	11 Sep 2020 11:25:37

US3762177

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:15:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 11:25:37

US3762177

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:15:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 11:25:37

US3762177

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 11:25:37

US3762177

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:15:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 11:25:37

US3762177

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered 'Jan 1983'	System	11 Sep 2020 11:25:37

US3762177

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered '1983'	System	11 Sep 2020 11:25:37

US3762177

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 11:25:37

US3762177

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 11:25:37

US3762177

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:15:26

[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)	11 Sep 2020 11:27:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 11:27:42
Data point term sent to Coder	System	11 Sep 2020 11:26:47
User entered 'Depression'	(b) (4), (b) (6)	11 Sep 2020 11:26:02

US3762177

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered '01 UNK 1998'	(b) (4), (b) (6)	11 Sep 2020 11:26:02

US3762177

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:15:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 11:26:02

US3762177

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:15:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 11:26:02

US3762177

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 11:26:02

US3762177

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:15:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 11:26:02

US3762177

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered 'Jan 1998'	System	11 Sep 2020 11:26:02

US3762177

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered '1998'	System	11 Sep 2020 11:26:02

US3762177

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 11:26:02

US3762177

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 11:26:02

US3762177

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:15:26

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Bladder and urethral symptoms, PT: Urinary incontinence, LLT: Urinary incontinence - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 11:27:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 11:27:42
Data point term sent to Coder	System	11 Sep 2020 11:26:47
User entered 'Urinary Incontinence'	(b) (4), (b) (6) (b) (4)	11 Sep 2020 11:26:42

US3762177

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered '01 UNK 2018'	(b) (4), (b) (6)	11 Sep 2020 11:26:42

US3762177

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:15:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 11:26:42

US3762177

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:15:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 11:26:42

US3762177

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 11:26:42

US3762177

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:15:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 11:26:42

US3762177

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	11 Sep 2020 11:26:42

US3762177

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered '2018'	System	11 Sep 2020 11:26:42

US3762177

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 11:26:42

US3762177

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 11:26:42

US3762177

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:15:26

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	13 Oct 2020 15:41:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	13 Oct 2020 15:41:18
Data point term sent to Coder	System	13 Oct 2020 15:40:01
User entered 'post menopausal'	Samantha Wheeler (b) (4)	13 Oct 2020 15:39:21
	(b) (4)	

US3762177

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered 'un UNK 2000'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:39:21

US3762177

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:15:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:39:21

US3762177

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:15:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:39:21

US3762177

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered empty.	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:39:21

US3762177

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:15:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:39:21

US3762177

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	13 Oct 2020 15:39:21

US3762177

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered '2000'	System	13 Oct 2020 15:39:21

US3762177

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 15:39:21

US3762177

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 15:39:21

US3762177

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:15:26

[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: Constipation, LLT: Constipation - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 18:02:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 18:02:24
Data point term sent to Coder	System	05 Nov 2020 18:01:30
User entered 'Frequent Constipation'	(b) (4), (b) (6)	05 Nov 2020 18:00:52

US3762177

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered 'UN UNK 2010'	(b) (4), (b) (6)	05 Nov 2020 18:00:52

US3762177

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:15:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 18:00:52

US3762177

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:15:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 18:00:52

US3762177

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 18:00:52

US3762177

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:15:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 18:00:52

US3762177

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	05 Nov 2020 18:00:52

US3762177

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered '2010'	System	05 Nov 2020 18:00:52

US3762177

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 18:00:52

US3762177

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 18:00:52

US3762177

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:15:26

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Hepatitis viral infections, PT: Hepatitis A, LLT: Hepatitis A - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 18:02:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 18:02:23
Data point term sent to Coder	System	05 Nov 2020 18:01:32
User entered 'Hepatitis A'	(b) (4), (b) (6)	05 Nov 2020 18:01:26

US3762177

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered 'UN UNK 1959'	(b) (4), (b) (6)	05 Nov 2020 18:01:26

US3762177

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:15:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 18:01:26

US3762177

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:15:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 18:01:26

US3762177

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered 'UN UNK 1959'	(b) (4), (b) (6)	05 Nov 2020 18:01:26

US3762177

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:15:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 18:01:26

US3762177

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered 'Jan 1959'	System	05 Nov 2020 18:01:26

US3762177

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered '1959'	System	05 Nov 2020 18:01:26

US3762177

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered 'Jan 1959'	System	05 Nov 2020 18:01:26

US3762177

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered '1959'	System	05 Nov 2020 18:01:26

US3762177

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:15:26

[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) (b) (4)	05 Nov 2020 18:03:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 18:03:21
Data point term sent to Coder	System	05 Nov 2020 18:02:33
User entered 'Irritable Bowel Syndrome'	(b) (4), (b) (6) (b) (4), (b) (6)	05 Nov 2020 18:02:03

US3762177

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered 'UN UNK 2010'	(b) (4), (b) (6)	05 Nov 2020 18:02:03

US3762177

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:15:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 18:02:03

US3762177

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:15:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 18:02:03

US3762177

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 18:02:03

US3762177

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:15:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 18:02:03

US3762177

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	05 Nov 2020 18:02:03

US3762177

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered '2010'	System	05 Nov 2020 18:02:03

US3762177

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 18:02:03

US3762177

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 18:02:03

US3762177

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:15:26

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Diverticulitis, LLT: Diverticulitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 18:03:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 18:03:22
Data point term sent to Coder	System	05 Nov 2020 18:02:33
User entered 'Diverticulitis'	(b) (4), (b) (6) (b) (4), (b) (6)	05 Nov 2020 18:02:27

US3762177

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered 'UN UNK 2002'	(b) (4), (b) (6)	05 Nov 2020 18:02:27

US3762177

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:15:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 18:02:27

US3762177

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:15:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 18:02:27

US3762177

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 18:02:27

US3762177

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:15:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 18:02:27

US3762177

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered 'Jan 2002'	System	05 Nov 2020 18:02:27

US3762177

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered '2002'	System	05 Nov 2020 18:02:27

US3762177

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 18:02:27

US3762177

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 18:02:27

US3762177

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:15:26

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Neck pain, LLT: Neck pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 18:04:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 18:04:21
Data point term sent to Coder	System	05 Nov 2020 18:03:34
User entered 'Neck Pain'	(b) (4), (b) (6)	05 Nov 2020 18:02:59

US3762177

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered 'UN UNK 1969'	(b) (4), (b) (6)	05 Nov 2020 18:02:59

US3762177

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:15:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 18:02:59

US3762177

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:15:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 18:02:59

US3762177

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 18:02:59

US3762177

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:15:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 18:02:59

US3762177

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered 'Jan 1969'	System	05 Nov 2020 18:02:59

US3762177

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered '1969'	System	05 Nov 2020 18:02:59

US3762177

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 18:02:59

US3762177

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 18:02:59

US3762177

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:15:26

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 18:05:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 18:05:22
Data point term sent to Coder	System	05 Nov 2020 18:04:36
User entered 'Osteoarthritis'	(b) (4), (b) (6)	05 Nov 2020 18:03:41

US3762177

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered 'UN UNK 2010'	(b) (4), (b) (6)	05 Nov 2020 18:03:41

US3762177

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:15:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 18:03:41

US3762177

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:15:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 18:03:41

US3762177

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 18:03:41

US3762177

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:15:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 18:03:41

US3762177

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	05 Nov 2020 18:03:41

US3762177

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered '2010'	System	05 Nov 2020 18:03:41

US3762177

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 18:03:41

US3762177

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 18:03:41

US3762177

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:15:26

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteopenia, LLT: Osteopenia - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 18:05:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 18:05:20
Data point term sent to Coder	System	05 Nov 2020 18:04:36
User entered 'Osteopenia'	(b) (4), (b) (6)	05 Nov 2020 18:04:24

US3762177

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered 'UN UNK 2010'	(b) (4), (b) (6)	05 Nov 2020 18:04:24

US3762177

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:15:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 18:04:24

US3762177

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:15:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 18:04:24

US3762177

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 18:04:24

US3762177

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:15:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 18:04:24

US3762177

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	05 Nov 2020 18:04:24

US3762177

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered '2010'	System	05 Nov 2020 18:04:24

US3762177

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 18:04:24

US3762177

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 18:04:24

US3762177

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:15:26

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Low back pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 18:06:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 18:06:23
Data point term sent to Coder	System	05 Nov 2020 18:05:40
User entered 'Lower Back Pain'	(b) (4), (b) (6)	05 Nov 2020 18:05:17

US3762177

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered 'UN UNK 2012'	(b) (4), (b) (6)	05 Nov 2020 18:05:17

US3762177

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:15:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 18:05:17

US3762177

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:15:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 18:05:17

US3762177

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 18:05:17

US3762177

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:15:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 18:05:17

US3762177

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered 'Jan 2012'	System	05 Nov 2020 18:05:17

US3762177

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered '2012'	System	05 Nov 2020 18:05:17

US3762177

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 18:05:17

US3762177

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 18:05:17

US3762177

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:15:26

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Mononeuropathies, PT: Carpal tunnel syndrome, LLT: Carpal tunnel syndrome - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 18:22:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 18:22:21
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Mononeuropathies, PT: Carpal tunnel syndrome, LLT: Carpal tunnel syndrome - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 18:07:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 18:07:21
Data point term sent to Coder	System	05 Nov 2020 18:06:41
User entered 'Carpal Tunnel Syndrome'	(b) (4), (b) (6) (b) (4), (b) (6)	05 Nov 2020 18:05:45

US3762177

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered 'UN UNK 2002'	(b) (4), (b) (6)	05 Nov 2020 18:05:45

US3762177

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:15:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 18:05:45

US3762177

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:15:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 18:05:45

US3762177

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 18:05:45

US3762177

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:15:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 18:05:45

US3762177

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered 'Jan 2002'	System	05 Nov 2020 18:05:45

US3762177

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered '2002'	System	05 Nov 2020 18:05:45

US3762177

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 18:05:45

US3762177

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 18:05:45

US3762177

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 11:36:41

US3762177

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered '03 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 11:36:41

US3762177

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:26

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '13:26'	(b) (4), (b) (6)	11 Sep 2020 11:36:41

US3762177

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered '03 Sep 2020 13:26'	System	11 Sep 2020 11:36:41

US3762177

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Sep 2020 11:36:55
User entered '63' in reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 11:36:55
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Sep 2020 11:36:41
User entered '63' (non-conformant).	(b) (4), (b) (6)	11 Sep 2020 11:36:41
DataPoint set to visible.	System	03 Sep 2020 18:05:15

US3762177

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Sep 2020 11:36:55
User entered '142' lb reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 11:36:55
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Sep 2020 11:36:41
User entered '142' (non-conformant).	(b) (4), (b) (6)	11 Sep 2020 11:36:41
DataPoint set to visible.	System	03 Sep 2020 18:05:15

US3762177

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:26

BMI (xxx.x)

Audit	User	Time (GMT)
User entered '25.20677'	System	11 Sep 2020 11:36:55
User entered empty.	System	11 Sep 2020 11:36:41
DataPoint set to visible.	System	03 Sep 2020 18:05:15

US3762177

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:26

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	11 Sep 2020 11:36:55
User entered empty.	System	11 Sep 2020 11:36:41
DataPoint set to visible.	System	03 Sep 2020 18:05:15

US3762177

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	11 Sep 2020 11:36:41

US3762177

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:26

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 11:36:41

US3762177

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:26

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 11:36:41

US3762177

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	11 Sep 2020 11:37:09
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	11 Sep 2020 11:37:09
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 11:37:09
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Sep 2020 11:36:41
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 11:36:41

US3762177

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:26

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	11 Sep 2020 11:37:09
User entered empty.	System	11 Sep 2020 11:36:41

US3762177

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	11 Sep 2020 11:36:41

US3762177

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	11 Sep 2020 11:36:41

US3762177

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	11 Sep 2020 11:36:41

US3762177

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Sep 2020 11:36:41

US3762177

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	11 Sep 2020 11:36:41

US3762177

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Sep 2020 11:36:41

US3762177

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 11:37:42

US3762177

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:26

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '03 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 11:37:42

US3762177

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered '03 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 11:38:30

US3762177

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 11:38:30

US3762177

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:15:26

If No, what is the reason?

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 13:27:36
Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' answered with 'will update' (Site from DM).	Samantha Wheeler (b) (4)	13 Oct 2020 15:38:54
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 05:39:57
User entered 'Post-menopausal (POST-MENOPAUSAL)'	(b) (4), (b) (6)	11 Sep 2020 11:38:30

US3762177

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 11:38:30

US3762177

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 11:38:30

US3762177

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:15:26

[Date of surgery unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 11:38:30

US3762177

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User closed query 'Date of last menstruation is provided, however, date of last menstruation unknown is checked. Please correct.' (Site from System).	System	13 Oct 2020 15:38:49
User opened query 'Date of last menstruation is provided, however, date of last menstruation unknown is checked. Please correct.' (Site from System).	System	13 Oct 2020 15:38:37
User entered 'un UNK 2000' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	13 Oct 2020 15:38:37
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	11 Sep 2020 11:38:30

US3762177

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:15:26

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
User entered '0' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	13 Oct 2020 15:38:49
User entered '1'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 11:38:30

US3762177

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 18:05:46

US3762177

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 18:05:46

US3762177

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 18:05:46

US3762177

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 18:05:46

US3762177

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 18:05:46

US3762177

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 18:05:46

US3762177

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 18:05:46

US3762177

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 18:05:46

US3762177

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 18:05:46

US3762177

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 18:05:46

US3762177

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 18:05:46

US3762177

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:26

[Other](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 18:05:46

US3762177

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:26

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 18:05:46

US3762177

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:26

No Risk Identified

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	03 Sep 2020 18:05:46

US3762177

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:26

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 18:05:46

US3762177

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 18:05:46

US3762177

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:26

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 18:05:46

US3762177

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:26

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 18:05:46

US3762177

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:26

Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 18:05:46

US3762177

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:26

[Other](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 18:05:46

US3762177

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:26

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 18:05:46

US3762177

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:15:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Samantha Wheeler (b) (4)	03 Sep 2020 18:25:10
	(b) (4)	

US3762177

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:15:26

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 01OCT2020 is reported under Visit 2 Day 29 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 11:53:27
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 01OCT2020 is reported under Visit 2 Day 29 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'Samples received ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 17:59:00
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 01OCT2020 is reported under Visit 2 Day 29 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 09:19:46
User entered '03 Sep 2020'	Samantha Wheeler (b) (4) (b) (4)	03 Sep 2020 18:25:10

US3762177

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Samantha Wheeler (b) (4) (b) (4)	03 Sep 2020 18:25:10

US3762177

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:15:26

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	03 Sep 2020 18:25:10

US3762177

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:15:26

What was the date of randomization? (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '03 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	03 Sep 2020 17:54:35

US3762177

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:15:26

What was the participant's randomization number?

Audit	User	Time (GMT)
User entered '189875'	RWS_ENDPOINT ENDPOINT (b) (4) 	03 Sep 2020 17:54:35

US3762177

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:15:26

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4) 	03 Sep 2020 17:54:35

US3762177

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:15:26

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 11:38:58

US3762177

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:15:26

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 11:38:58

US3762177

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:15:26

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 11:38:58

US3762177

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:15:26

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 11:38:58

US3762177

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:15:26

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 11:38:58

US3762177

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:15:26

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 18:06:11
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:14:29
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:14:27

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:15:26

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:15:26

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:15:26

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:15:26

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:26

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '03 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:26

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '13:26'	(b) (4), (b) (6)	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered '03 Sep 2020 13:26'	System	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:26

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.0' F	(b) (4), (b) (6)	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:26

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:26

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '68'	(b) (4), (b) (6)	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:26

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered '16'	(b) (4), (b) (6)	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '104'	(b) (4), (b) (6)	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '67'	(b) (4), (b) (6)	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:15:26

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:15:26

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:26

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '03 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:26

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '14:57'	(b) (4), (b) (6)	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered '03 Sep 2020 14:57'	System	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:26

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.7' F	(b) (4), (b) (6)	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:26

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:26

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '68'	(b) (4), (b) (6)	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:26

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered '16'	(b) (4), (b) (6)	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '119'	(b) (4), (b) (6)	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '67'	(b) (4), (b) (6)	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Sep 2020 11:42:54

US3762177

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 11:43:05

US3762177

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:26

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 11:43:05

US3762177

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:26

[Was study treatment given?](#)

Audit	User	Time (GMT)
User closed query 'Was study treatment given? Is No but any of these is present: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	03 Sep 2020 18:25:59
Query 'Was study treatment given? Is No but any of these is present: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' answered by data change (Site from System).	System	03 Sep 2020 18:25:59
User entered 'Yes (Y)' reason for change: Data Entry Error	Samantha Wheeler (b) (4) (b) (4)	03 Sep 2020 18:25:59
User opened query 'Was study treatment given? Is No but any of these is present: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	03 Sep 2020 18:08:33
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 18:08:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 18:08:00

US3762177

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:26

[If No, reason not given](#)

Audit	User	Time (GMT)
User closed query 'Was study treatment given? is No, System however If No, reason not given is not provided. Please review and reconcile.' (Site from System).		03 Sep 2020 18:25:59
User opened query 'Was study treatment given? is No, however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	System	03 Sep 2020 18:08:33
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 18:08:00

US3762177

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 18:08:00

US3762177

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:26

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	03 Sep 2020 18:25:59
User entered empty.	System	03 Sep 2020 18:08:33
User entered 'MRNA-1273 OR PLACEBO'	System	03 Sep 2020 18:08:00

US3762177

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:26

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '3 Sep 2020'	(b) (4), (b) (6)	03 Sep 2020 18:08:00

US3762177

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:26

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '14:19' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	03 Sep 2020 18:25:59
User entered '14:02'	(b) (4), (b) (6)	03 Sep 2020 18:08:00

US3762177

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:26

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '3 Sep 2020 14:19'	System	03 Sep 2020 18:25:59
User entered '3 Sep 2020 14:02'	System	03 Sep 2020 18:08:00

US3762177

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:26

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User entered 'Right Arm (RIGHT ARM)' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	03 Sep 2020 18:25:59
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	03 Sep 2020 18:08:00

US3762177

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:26

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	03 Sep 2020 18:25:59
User entered empty.	System	03 Sep 2020 18:08:33
User entered 'ONCE'	System	03 Sep 2020 18:08:00

US3762177

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:26

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	03 Sep 2020 18:25:59
User entered empty.	System	03 Sep 2020 18:08:33
User entered 'INTRAMUSCULAR'	System	03 Sep 2020 18:08:00

US3762177

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 11:43:30

US3762177

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '03 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 11:43:30

US3762177

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:26

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '13:40'	(b) (4), (b) (6)	11 Sep 2020 11:43:30

US3762177

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:26

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 13:40'	System	11 Sep 2020 11:43:30

US3762177

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:15:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '03 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 11:43:50

US3762177

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:15:26

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	11 Sep 2020 11:43:50

US3762177

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:15:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 11:43:50

US3762177

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:15:26

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered '13:44'	(b) (4), (b) (6)	11 Sep 2020 11:43:50

US3762177

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:15:26

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 13:44'	System	11 Sep 2020 11:43:50

US3762177

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:15:26

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	11 Sep 2020 11:43:50

US3762177

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:15:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 11:43:50

US3762177

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:15:26

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 11:43:50

US3762177

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:15:26

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 11:43:50

US3762177

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:15:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 11:44:02

US3762177

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:15:26

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 11:44:02

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 18:08:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:15:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T14:49:53', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'de3b0d8e-f337-4bc7-983f-2faaf0505ae2'	System	03 Sep 2020 18:50:26
User entered 'Yes (Y)'	System	03 Sep 2020 18:50:26

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:15:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T14:50:00', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'de3b0d8e-f337-4bc7-983f-2faaf0505ae2'	System	03 Sep 2020 18:50:26
User entered '97.7'	System	03 Sep 2020 18:50:26

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T14:50:09', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'de3b0d8e-f337-4bc7-983f-2faaf0505ae2'	System	03 Sep 2020 18:50:26
User entered 'No (N)'	System	03 Sep 2020 18:50:26

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:15:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T14:50:21', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'de3b0d8e-f337-4bc7-983f-2faaf0505ae2'	System	03 Sep 2020 18:50:26
User entered '03 Sep 2020 14:50'	System	03 Sep 2020 18:50:26

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 14:39'	System	03 Sep 2020 18:25:59
User entered '03 Sep 2020 14:22'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 17:09'	System	03 Sep 2020 18:25:59
User entered '03 Sep 2020 16:52'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 18:08:00
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:15:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T21:48:19', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '2de67cc9-5c78-4e21-b2ac-a3ce4ca811af'	System	04 Sep 2020 01:48:40
User entered 'Yes (Y)'	System	04 Sep 2020 01:48:40

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:15:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T21:48:26', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '2de67cc9-5c78-4e21-b2ac-a3ce4ca811af' User entered '97.3'	System	04 Sep 2020 01:48:40
	System	04 Sep 2020 01:48:40

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T21:48:30', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '2de67cc9-5c78-4e21-b2ac-a3ce4ca811af'	System	04 Sep 2020 01:48:40
User entered 'No (N)'	System	04 Sep 2020 01:48:40

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:15:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T21:48:37', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '2de67cc9-5c78-4e21-b2ac-a3ce4ca811af'	System	04 Sep 2020 01:48:40
User entered '03 Sep 2020 21:48'	System	04 Sep 2020 01:48:40

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 18:04'	System	03 Sep 2020 18:25:59
User entered '03 Sep 2020 17:47'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 18:08:00
User entered 'Day 2'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:15:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-04T18:48:56', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'a6c437ca-22a9-4e3e-90d0-1fb31c47bd98'	System	04 Sep 2020 22:49:21
User entered 'Yes (Y)'	System	04 Sep 2020 22:49:21

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:15:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-04T18:49:04', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'a6c437ca-22a9-4e3e-90d0-1fb31c47bd98'	System	04 Sep 2020 22:49:21
User entered '98.6'	System	04 Sep 2020 22:49:21

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-04T18:49:09', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'a6c437ca-22a9-4e3e-90d0-1fb31c47bd98'	System	04 Sep 2020 22:49:21
User entered 'No (N)'	System	04 Sep 2020 22:49:21

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:15:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-04T18:49:17', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'a6c437ca-22a9-4e3e-90d0-1fb31c47bd98'	System	04 Sep 2020 22:49:21
User entered '04 Sep 2020 18:49'	System	04 Sep 2020 22:49:21

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 18:08:00
User entered 'Day 3'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:15:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-05T21:05:32', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fbff7fb1-3673-4b55-8518-ab665ca0e215'	System	06 Sep 2020 01:06:00
User entered 'Yes (Y)'	System	06 Sep 2020 01:06:00

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:15:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-05T21:05:38', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fbff7fb1-3673-4b55-8518-ab665ca0e215'	System	06 Sep 2020 01:06:00
User entered '97.1'	System	06 Sep 2020 01:06:00

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-05T21:05:43', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fbff7fb1-3673-4b55-8518-ab665ca0e215'	System	06 Sep 2020 01:06:00
User entered 'Yes (Y)'	System	06 Sep 2020 01:06:00

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	16 Oct 2020 12:30:28
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'omeprazole and immodium taken' (Site from System).	Samantha Wheeler (b) (4)	13 Oct 2020 15:16:26
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	06 Sep 2020 01:06:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-05T21:05:52', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fbff7fb1-3673-4b55-8518-ab665ca0e215'	System	06 Sep 2020 01:06:00
User entered '1'	System	06 Sep 2020 01:06:00

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:15:26

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-05T21:05:52', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fbff7fb1-3673-4b55-8518-ab665ca0e215'	System	06 Sep 2020 01:06:00
User entered '0'	System	06 Sep 2020 01:06:00

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:15:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-05T21:05:56', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fbff7fb1-3673-4b55-8518-ab665ca0e215'	System	06 Sep 2020 01:06:00
User entered '05 Sep 2020 21:05'	System	06 Sep 2020 01:06:00

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 18:08:00
User entered 'Day 4'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:15:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-06T19:51:41', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '085b4a1f-b059-40fe-a898-0a0159cfd637'	System	06 Sep 2020 23:52:08
User entered 'Yes (Y)'	System	06 Sep 2020 23:52:08

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:15:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-06T19:51:50', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '085b4a1f-b059-40fe-a898-0a0159cfd637'	System	06 Sep 2020 23:52:08
User entered '98.5'	System	06 Sep 2020 23:52:08

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-06T19:51:57', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '085b4a1f-b059-40fe-a898-0a0159cfd637'	System	06 Sep 2020 23:52:08
User entered 'No (N)'	System	06 Sep 2020 23:52:08

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:15:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-06T19:52:03', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '085b4a1f-b059-40fe-a898-0a0159cfd637'	System	06 Sep 2020 23:52:08
User entered '06 Sep 2020 19:52'	System	06 Sep 2020 23:52:08

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 18:08:00
User entered 'Day 5'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:15:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-07T20:21:50', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '501202e7-5fe6-4129-8fb7-69797ccb30b7'	System	08 Sep 2020 00:22:22
User entered 'Yes (Y)'	System	08 Sep 2020 00:22:22

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:15:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-07T20:22:04', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '501202e7-5fe6-4129-8fb7-69797ccb30b7'	System	08 Sep 2020 00:22:22
User entered '97.9'	System	08 Sep 2020 00:22:22

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-07T20:22:09', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '501202e7-5fe6-4129-8fb7-69797ccb30b7'	System	08 Sep 2020 00:22:22
User entered 'Yes (Y)'	System	08 Sep 2020 00:22:22

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	16 Oct 2020 12:45:36
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'omeprazole and immodium taken' (Site from System).	Samantha Wheeler (b) (4)	13 Oct 2020 15:16:56
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	08 Sep 2020 00:22:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-07T20:22:15', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '501202e7-5fe6-4129-8fb7-69797ccb30b7'	System	08 Sep 2020 00:22:22
User entered '1'	System	08 Sep 2020 00:22:22

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:15:26

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-07T20:22:15', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '501202e7-5fe6-4129-8fb7-69797ccb30b7'	System	08 Sep 2020 00:22:22
User entered '0'	System	08 Sep 2020 00:22:22

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:15:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-07T20:22:19', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '501202e7-5fe6-4129-8fb7-69797ccb30b7'	System	08 Sep 2020 00:22:22
User entered '07 Sep 2020 20:22'	System	08 Sep 2020 00:22:22

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 18:08:00
User entered 'Day 6'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:15:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-08T21:28:17', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '85c021f0-113d-4e80-b9bc-de47ad6e4c70'	System	09 Sep 2020 01:28:39
User entered 'Yes (Y)'	System	09 Sep 2020 01:28:39

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:15:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-08T21:28:24', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '85c021f0-113d-4e80-b9bc-de47ad6e4c70'	System	09 Sep 2020 01:28:39
User entered '98.1'	System	09 Sep 2020 01:28:39

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-08T21:28:32', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '85c021f0-113d-4e80-b9bc-de47ad6e4c70'	System	09 Sep 2020 01:28:39
User entered 'No (N)'	System	09 Sep 2020 01:28:39

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:15:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-08T21:28:35', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '85c021f0-113d-4e80-b9bc-de47ad6e4c70'	System	09 Sep 2020 01:28:39
User entered '08 Sep 2020 21:28'	System	09 Sep 2020 01:28:39

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 18:08:00
User entered 'Day 7'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:15:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-09T20:50:27', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '6a7319f8-c349-48d3-8faf-073c91436293'	System	10 Sep 2020 00:50:46
User entered 'Yes (Y)'	System	10 Sep 2020 00:50:46

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:15:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-09T20:50:33', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '6a7319f8-c349-48d3-8faf-073c91436293'	System	10 Sep 2020 00:50:46
User entered '98.0'	System	10 Sep 2020 00:50:46

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-09T20:50:37', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '6a7319f8-c349-48d3-8faf-073c91436293'	System	10 Sep 2020 00:50:46
User entered 'No (N)'	System	10 Sep 2020 00:50:46

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:15:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-09T20:50:41', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '6a7319f8-c349-48d3-8faf-073c91436293'	System	10 Sep 2020 00:50:46
User entered '09 Sep 2020 20:50'	System	10 Sep 2020 00:50:46

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 18:08:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:15:26

[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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T14:50:44', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '1eb33bd2-c697-47dd-b8d8-ec13bc4d19f3'	System	03 Sep 2020 18:51:22
User entered 'None (1)'	System	03 Sep 2020 18:51:22

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:15:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T14:51:03', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '1eb33bd2-c697-47dd-b8d8-ec13bc4d19f3'	System	03 Sep 2020 18:51:22
User entered 'No (N)'	System	03 Sep 2020 18:51:22

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T14:51:07', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '1eb33bd2-c697-47dd-b8d8-ec13bc4d19f3'	System	03 Sep 2020 18:51:22
User entered 'No (N)'	System	03 Sep 2020 18:51:22

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:15:26

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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T14:51:13', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '1eb33bd2-c697-47dd-b8d8-ec13bc4d19f3'	System	03 Sep 2020 18:51:22
User entered 'None (1)'	System	03 Sep 2020 18:51:22

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:15:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T14:51:19', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '1eb33bd2-c697-47dd-b8d8-ec13bc4d19f3'	System	03 Sep 2020 18:51:22
User entered '03 Sep 2020 14:51'	System	03 Sep 2020 18:51:22

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 14:39'	System	03 Sep 2020 18:25:59
User entered '03 Sep 2020 14:22'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 17:09'	System	03 Sep 2020 18:25:59
User entered '03 Sep 2020 16:52'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 18:08:00
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:26

[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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T21:50:29', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fbfed41e-76c3-4f87-a9ee-91e36def3a81'	System	04 Sep 2020 01:55:02
User entered 'Does not interfere with activity (2)'	System	04 Sep 2020 01:55:02

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T21:52:34', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fbfed41e-76c3-4f87-a9ee-91e36def3a81'	System	04 Sep 2020 01:55:02
User entered 'Yes (Y)'	System	04 Sep 2020 01:55:02

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:26

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

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T21:52:51', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fbfed41e-76c3-4f87-a9ee-91e36def3a81' User entered '20'	System	04 Sep 2020 01:55:02
	System	04 Sep 2020 01:55:02

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T21:53:07', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fbfed41e-76c3-4f87-a9ee-91e36def3a81'	System	04 Sep 2020 01:55:02
User entered 'Yes (Y)'	System	04 Sep 2020 01:55:02

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:26

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

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T21:54:34', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fbfed41e-76c3-4f87-a9ee-91e36def3a81' User entered '4'	System	04 Sep 2020 01:55:02
	System	04 Sep 2020 01:55:02

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:26

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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T21:54:46', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fbfed41e-76c3-4f87-a9ee-91e36def3a81'	System	04 Sep 2020 01:55:02
User entered 'None (1)'	System	04 Sep 2020 01:55:02

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T21:54:58', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fbfed41e-76c3-4f87-a9ee-91e36def3a81'	System	04 Sep 2020 01:55:02
User entered '03 Sep 2020 21:54'	System	04 Sep 2020 01:55:02

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 18:04'	System	03 Sep 2020 18:25:59
User entered '03 Sep 2020 17:47'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 18:08:00
User entered 'Day 2'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:26

[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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-04T18:49:35', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '2fdc6f30-234f-4d37-9dc2-c382e327e237'	System	04 Sep 2020 22:53:07
User entered 'Does not interfere with activity (2)'	System	04 Sep 2020 22:53:07

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-04T18:49:39', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '2fdc6f30-234f-4d37-9dc2-c382e327e237'	System	04 Sep 2020 22:53:07
User entered 'Yes (Y)'	System	04 Sep 2020 22:53:07

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:26

Please record - REDNESS AT INJECTION SITE (in mm)

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-04T18:49:56', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '2fdc6f30-234f-4d37-9dc2-c382e327e237'	System	04 Sep 2020 22:53:07
User entered '65'	System	04 Sep 2020 22:53:07

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-04T18:50:01', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '2fdc6f30-234f-4d37-9dc2-c382e327e237'	System	04 Sep 2020 22:53:07
User entered 'Yes (Y)'	System	04 Sep 2020 22:53:07

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:26

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

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-04T18:52:34', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '2fdc6f30-234f-4d37-9dc2-c382e327e237'	System	04 Sep 2020 22:53:07
User entered '30'	System	04 Sep 2020 22:53:07

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:26

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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-04T18:52:47', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '2fdc6f30-234f-4d37-9dc2-c382e327e237'	System	04 Sep 2020 22:53:07
User entered 'None (1)'	System	04 Sep 2020 22:53:07

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-04T18:53:02', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '2fdc6f30-234f-4d37-9dc2-c382e327e237'	System	04 Sep 2020 22:53:07
User entered '04 Sep 2020 18:53'	System	04 Sep 2020 22:53:07

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 18:08:00
User entered 'Day 3'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:26

[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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-05T21:06:07', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '61446f65-9486-4a6f-a2b9-56bb2aa33370'	System	06 Sep 2020 01:06:44
User entered 'Does not interfere with activity (2)'	System	06 Sep 2020 01:06:44

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-05T21:06:11', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '61446f65-9486-4a6f-a2b9-56bb2aa33370'	System	06 Sep 2020 01:06:44
User entered 'Yes (Y)'	System	06 Sep 2020 01:06:44

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:26

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

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-05T21:06:20', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '61446f65-9486-4a6f-a2b9-56bb2aa33370' User entered '95'	System	06 Sep 2020 01:06:44
	System	06 Sep 2020 01:06:44

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-05T21:06:25', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '61446f65-9486-4a6f-a2b9-56bb2aa33370'	System	06 Sep 2020 01:06:44
User entered 'Yes (Y)'	System	06 Sep 2020 01:06:44

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:26

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

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-05T21:06:33', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '61446f65-9486-4a6f-a2b9-56bb2aa33370' User entered '30'	System	06 Sep 2020 01:06:44
	System	06 Sep 2020 01:06:44

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:26

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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-05T21:06:38', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '61446f65-9486-4a6f-a2b9-56bb2aa33370'	System	06 Sep 2020 01:06:44
User entered 'None (1)'	System	06 Sep 2020 01:06:44

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-05T21:06:41', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '61446f65-9486-4a6f-a2b9-56bb2aa33370'	System	06 Sep 2020 01:06:44
User entered '05 Sep 2020 21:06'	System	06 Sep 2020 01:06:44

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:15:26

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 18:08:00
User entered 'Day 4'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:15:26

[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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-06T19:52:16', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '40833206-30f3-4d7c-82fb-9bfd9b8db552'	System	06 Sep 2020 23:52:47
User entered 'Does not interfere with activity (2)'	System	06 Sep 2020 23:52:47

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:15:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-06T19:52:20', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '40833206-30f3-4d7c-82fb-9bfd9b8db552'	System	06 Sep 2020 23:52:47
User entered 'Yes (Y)'	System	06 Sep 2020 23:52:47

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:15:26

Please record - REDNESS AT INJECTION SITE (in mm)

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-06T19:52:28', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '40833206-30f3-4d7c-82fb-9bfd9b8db552'	System	06 Sep 2020 23:52:47
User entered '110'	System	06 Sep 2020 23:52:47

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-06T19:52:34', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '40833206-30f3-4d7c-82fb-9bfd9b8db552'	System	06 Sep 2020 23:52:47
User entered 'Yes (Y)'	System	06 Sep 2020 23:52:47

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:15:26

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

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-06T19:52:38', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '40833206-30f3-4d7c-82fb-9bfd9b8db552'	System	06 Sep 2020 23:52:47
User entered '30'	System	06 Sep 2020 23:52:47

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:15:26

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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-06T19:52:42', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '40833206-30f3-4d7c-82fb-9bfd9b8db552'	System	06 Sep 2020 23:52:47
User entered 'None (1)'	System	06 Sep 2020 23:52:47

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:15:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-06T19:52:45', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '40833206-30f3-4d7c-82fb-9bfd9b8db552'	System	06 Sep 2020 23:52:47
User entered '06 Sep 2020 19:52'	System	06 Sep 2020 23:52:47

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 18:08:00
User entered 'Day 5'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:15:26

[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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-07T20:22:35', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'da82b94f-20cb-4b06-b62b-3c10bc1bf11f'	System	08 Sep 2020 00:23:20
User entered 'Does not interfere with activity (2)'	System	08 Sep 2020 00:23:20

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:15:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-07T20:22:38', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'da82b94f-20cb-4b06-b62b-3c10bc1bf11f'	System	08 Sep 2020 00:23:20
User entered 'Yes (Y)'	System	08 Sep 2020 00:23:20

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:15:26

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

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-07T20:22:55', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'da82b94f-20cb-4b06-b62b-3c10bc1bf11f' User entered '80'	System	08 Sep 2020 00:23:20
	System	08 Sep 2020 00:23:20

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-07T20:23:08', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'da82b94f-20cb-4b06-b62b-3c10bc1bf11f'	System	08 Sep 2020 00:23:20
User entered 'Yes (Y)'	System	08 Sep 2020 00:23:20

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:15:26

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

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-07T20:23:12', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'da82b94f-20cb-4b06-b62b-3c10bc1bf11f' User entered '20'	System	08 Sep 2020 00:23:20
	System	08 Sep 2020 00:23:20

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:15:26

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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-07T20:23:16', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'da82b94f-20cb-4b06-b62b-3c10bc1bf11f'	System	08 Sep 2020 00:23:20
User entered 'None (1)'	System	08 Sep 2020 00:23:20

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:15:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-07T20:23:19', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'da82b94f-20cb-4b06-b62b-3c10bc1bf11f'	System	08 Sep 2020 00:23:20
User entered '07 Sep 2020 20:23'	System	08 Sep 2020 00:23:20

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 18:08:00
User entered 'Day 6'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:15:26

[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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-08T21:28:49', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'd3e73ca1-717d-4c57-a3e4-60ea96c5df0b'	System	09 Sep 2020 01:29:25
User entered 'None (1)'	System	09 Sep 2020 01:29:25

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:15:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-08T21:28:52', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'd3e73ca1-717d-4c57-a3e4-60ea96c5df0b'	System	09 Sep 2020 01:29:25
User entered 'Yes (Y)'	System	09 Sep 2020 01:29:25

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:15:26

Please record - REDNESS AT INJECTION SITE (in mm)

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-08T21:28:57', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'd3e73ca1-717d-4c57-a3e4-60ea96c5df0b' User entered '80'	System	09 Sep 2020 01:29:25
	System	09 Sep 2020 01:29:25

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-08T21:29:01', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'd3e73ca1-717d-4c57-a3e4-60ea96c5df0b'	System	09 Sep 2020 01:29:25
User entered 'Yes (Y)'	System	09 Sep 2020 01:29:25

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:15:26

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

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-08T21:29:05', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'd3e73ca1-717d-4c57-a3e4-60ea96c5df0b' User entered '20'	System	09 Sep 2020 01:29:25
	System	09 Sep 2020 01:29:25

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:15:26

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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-08T21:29:09', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'd3e73ca1-717d-4c57-a3e4-60ea96c5df0b'	System	09 Sep 2020 01:29:25
User entered 'None (1)'	System	09 Sep 2020 01:29:25

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:15:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-08T21:29:21', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'd3e73ca1-717d-4c57-a3e4-60ea96c5df0b'	System	09 Sep 2020 01:29:25
User entered '08 Sep 2020 21:29'	System	09 Sep 2020 01:29:25

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 18:08:00
User entered 'Day 7'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:15:26

[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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-09T20:50:49', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '9b20e07b-4f1f-4cd2-af73-2e77510c6e77'	System	10 Sep 2020 00:51:08
User entered 'None (1)'	System	10 Sep 2020 00:51:08

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:15:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-09T20:50:52', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '9b20e07b-4f1f-4cd2-af73-2e77510c6e77'	System	10 Sep 2020 00:51:08
User entered 'Yes (Y)'	System	10 Sep 2020 00:51:08

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:15:26

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

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-09T20:50:57', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '9b20e07b-4f1f-4cd2-af73-2e77510c6e77'	System	10 Sep 2020 00:51:08
User entered '60'	System	10 Sep 2020 00:51:08

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-09T20:51:00', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '9b20e07b-4f1f-4cd2-af73-2e77510c6e77'	System	10 Sep 2020 00:51:08
User entered 'No (N)'	System	10 Sep 2020 00:51:08

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:15:26

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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-09T20:51:04', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '9b20e07b-4f1f-4cd2-af73-2e77510c6e77'	System	10 Sep 2020 00:51:08
User entered 'None (1)'	System	10 Sep 2020 00:51:08

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:15:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-09T20:51:07', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '9b20e07b-4f1f-4cd2-af73-2e77510c6e77'	System	10 Sep 2020 00:51:08
User entered '09 Sep 2020 20:51'	System	10 Sep 2020 00:51:08

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 18:08:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:26

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T14:51:26', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '36bb0177-3201-4ddd-a0d1-830de70e1203'	System	03 Sep 2020 18:52:05
User entered 'None (0)'	System	03 Sep 2020 18:52:05

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:26

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T14:51:30', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '36bb0177-3201-4ddd-a0d1-830de70e1203'	System	03 Sep 2020 18:52:05
User entered 'None (0)'	System	03 Sep 2020 18:52:05

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T14:51:33', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '36bb0177-3201-4ddd-a0d1-830de70e1203'	System	03 Sep 2020 18:52:05
User entered 'None (0)'	System	03 Sep 2020 18:52:05

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T14:51:36', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '36bb0177-3201-4ddd-a0d1-830de70e1203'	System	03 Sep 2020 18:52:05
User entered 'None (0)'	System	03 Sep 2020 18:52:05

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T14:51:40', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '36bb0177-3201-4ddd-a0d1-830de70e1203'	System	03 Sep 2020 18:52:05
User entered 'None (0)'	System	03 Sep 2020 18:52:05

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:26

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T14:51:42', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '36bb0177-3201-4ddd-a0d1-830de70e1203'	System	03 Sep 2020 18:52:05
User entered 'None (0)'	System	03 Sep 2020 18:52:05

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:26

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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T14:51:58', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '36bb0177-3201-4ddd-a0d1-830de70e1203'	System	03 Sep 2020 18:52:05
User entered 'No (N)'	System	03 Sep 2020 18:52:05

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:26

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T14:52:04', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '36bb0177-3201-4ddd-a0d1-830de70e1203'	System	03 Sep 2020 18:52:05
User entered '03 Sep 2020 14:52'	System	03 Sep 2020 18:52:05

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 14:39'	System	03 Sep 2020 18:25:59
User entered '03 Sep 2020 14:22'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 17:09'	System	03 Sep 2020 18:25:59
User entered '03 Sep 2020 16:52'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 18:08:00
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:26

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T21:55:06', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'ef164707-e06c-4d34-83ff-5c0a0f8fe390'	System	04 Sep 2020 01:55:29
User entered 'None (0)'	System	04 Sep 2020 01:55:29

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:26

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T21:55:09', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'ef164707-e06c-4d34-83ff-5c0a0f8fe390'	System	04 Sep 2020 01:55:29
User entered 'None (0)'	System	04 Sep 2020 01:55:29

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T21:55:12', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'ef164707-e06c-4d34-83ff-5c0a0f8fe390'	System	04 Sep 2020 01:55:29
User entered 'None (0)'	System	04 Sep 2020 01:55:29

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T21:55:15', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'ef164707-e06c-4d34-83ff-5c0a0f8fe390'	System	04 Sep 2020 01:55:29
User entered 'None (0)'	System	04 Sep 2020 01:55:29

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T21:55:18', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'ef164707-e06c-4d34-83ff-5c0a0f8fe390'	System	04 Sep 2020 01:55:29
User entered 'None (0)'	System	04 Sep 2020 01:55:29

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:26

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T21:55:20', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'ef164707-e06c-4d34-83ff-5c0a0f8fe390'	System	04 Sep 2020 01:55:29
User entered 'None (0)'	System	04 Sep 2020 01:55:29

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:26

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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T21:55:24', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'ef164707-e06c-4d34-83ff-5c0a0f8fe390'	System	04 Sep 2020 01:55:29
User entered 'No (N)'	System	04 Sep 2020 01:55:29

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:26

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-03T21:55:27', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'ef164707-e06c-4d34-83ff-5c0a0f8fe390'	System	04 Sep 2020 01:55:29
User entered '03 Sep 2020 21:55'	System	04 Sep 2020 01:55:29

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 18:04'	System	03 Sep 2020 18:25:59
User entered '03 Sep 2020 17:47'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 18:08:00
User entered 'Day 2'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:26

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-04T18:53:11', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'e9b33371-5806-4bee-9e3f-2fbfd2903929'	System	04 Sep 2020 22:54:30
User entered 'No interference with activity (1)'	System	04 Sep 2020 22:54:30

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:26

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-04T18:53:24', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'e9b33371-5806-4bee-9e3f-2fbfd2903929'	System	04 Sep 2020 22:54:30
User entered 'Some interference with activity (2)'	System	04 Sep 2020 22:54:30

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-04T18:53:30', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'e9b33371-5806-4bee-9e3f-2fbfd2903929'	System	04 Sep 2020 22:54:30
User entered 'No interference with activity (1)'	System	04 Sep 2020 22:54:30

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-04T18:53:53', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'e9b33371-5806-4bee-9e3f-2fbfd2903929'	System	04 Sep 2020 22:54:30
User entered 'None (0)'	System	04 Sep 2020 22:54:30

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-04T18:54:00', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'e9b33371-5806-4bee-9e3f-2fbfd2903929'	System	04 Sep 2020 22:54:30
User entered 'None (0)'	System	04 Sep 2020 22:54:30

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:26

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-04T18:54:05', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'e9b33371-5806-4bee-9e3f-2fbfd2903929'	System	04 Sep 2020 22:54:30
User entered 'None (0)'	System	04 Sep 2020 22:54:30

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:26

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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-04T18:54:12', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'e9b33371-5806-4bee-9e3f-2fbfd2903929'	System	04 Sep 2020 22:54:30
User entered 'No (N)'	System	04 Sep 2020 22:54:30

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:26

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-04T18:54:24', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'e9b33371-5806-4bee-9e3f-2fbfd2903929'	System	04 Sep 2020 22:54:30
User entered '04 Sep 2020 18:54'	System	04 Sep 2020 22:54:30

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 18:08:00
User entered 'Day 3'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:26

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-05T21:06:49', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fb807188-c727-4ed8-8544-286dfe0f99c3'	System	06 Sep 2020 01:07:44
User entered 'None (0)'	System	06 Sep 2020 01:07:44

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:26

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-05T21:06:54', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fb807188-c727-4ed8-8544-286dfe0f99c3'	System	06 Sep 2020 01:07:44
User entered 'No interference with activity (1)'	System	06 Sep 2020 01:07:44

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-05T21:07:06', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fb807188-c727-4ed8-8544-286dfe0f99c3'	System	06 Sep 2020 01:07:44
User entered 'No interference with activity (1)'	System	06 Sep 2020 01:07:44

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-05T21:07:11', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fb807188-c727-4ed8-8544-286dfe0f99c3'	System	06 Sep 2020 01:07:44
User entered 'None (0)'	System	06 Sep 2020 01:07:44

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-05T21:07:15', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fb807188-c727-4ed8-8544-286dfe0f99c3'	System	06 Sep 2020 01:07:44
User entered 'None (0)'	System	06 Sep 2020 01:07:44

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:26

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-05T21:07:23', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fb807188-c727-4ed8-8544-286dfe0f99c3'	System	06 Sep 2020 01:07:44
User entered 'No interference with activity (1)'	System	06 Sep 2020 01:07:44

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:26

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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-05T21:07:28', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fb807188-c727-4ed8-8544-286dfe0f99c3'	System	06 Sep 2020 01:07:44
User entered 'No (N)'	System	06 Sep 2020 01:07:44

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:26

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-05T21:07:41', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fb807188-c727-4ed8-8544-286dfe0f99c3'	System	06 Sep 2020 01:07:44
User entered '05 Sep 2020 21:07'	System	06 Sep 2020 01:07:44

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 18:08:00
User entered 'Day 4'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:26

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-06T19:52:50', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '1ac2caf8-1ec0-4abc-afc8-786d49318b2d'	System	06 Sep 2020 23:53:34
User entered 'None (0)'	System	06 Sep 2020 23:53:34

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:26

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-06T19:52:54', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '1ac2caf8-1ec0-4abc-afc8-786d49318b2d'	System	06 Sep 2020 23:53:34
User entered 'No interference with activity (1)'	System	06 Sep 2020 23:53:34

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-06T19:53:00', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '1ac2caf8-1ec0-4abc-afc8-786d49318b2d'	System	06 Sep 2020 23:53:34
User entered 'No interference with activity (1)'	System	06 Sep 2020 23:53:34

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-06T19:53:04', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '1ac2caf8-1ec0-4abc-afc8-786d49318b2d'	System	06 Sep 2020 23:53:34
User entered 'None (0)'	System	06 Sep 2020 23:53:34

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-06T19:53:07', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '1ac2caf8-1ec0-4abc-afc8-786d49318b2d'	System	06 Sep 2020 23:53:34
User entered 'None (0)'	System	06 Sep 2020 23:53:34

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:26

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-06T19:53:10', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '1ac2caf8-1ec0-4abc-afc8-786d49318b2d'	System	06 Sep 2020 23:53:34
User entered 'None (0)'	System	06 Sep 2020 23:53:34

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:26

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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-06T19:53:17', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '1ac2caf8-1ec0-4abc-afc8-786d49318b2d'	System	06 Sep 2020 23:53:34
User entered 'No (N)'	System	06 Sep 2020 23:53:34

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:26

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-06T19:53:30', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '1ac2caf8-1ec0-4abc-afc8-786d49318b2d'	System	06 Sep 2020 23:53:34
User entered '06 Sep 2020 19:53'	System	06 Sep 2020 23:53:34

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 18:08:00
User entered 'Day 5'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:26

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-07T20:23:26', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '3aa67c7d-2ac6-42bd-bfc0-252e042b3b7b'	System	08 Sep 2020 00:24:04
User entered 'None (0)'	System	08 Sep 2020 00:24:04

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:26

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-07T20:23:29', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '3aa67c7d-2ac6-42bd-bfc0-252e042b3b7b'	System	08 Sep 2020 00:24:04
User entered 'No interference with activity (1)'	System	08 Sep 2020 00:24:04

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-07T20:23:36', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '3aa67c7d-2ac6-42bd-bfc0-252e042b3b7b'	System	08 Sep 2020 00:24:04
User entered 'No interference with activity (1)'	System	08 Sep 2020 00:24:04

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-07T20:23:40', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '3aa67c7d-2ac6-42bd-bfc0-252e042b3b7b'	System	08 Sep 2020 00:24:04
User entered 'No interference with activity (1)'	System	08 Sep 2020 00:24:04

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-07T20:23:42', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '3aa67c7d-2ac6-42bd-bfc0-252e042b3b7b'	System	08 Sep 2020 00:24:04
User entered 'None (0)'	System	08 Sep 2020 00:24:04

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:26

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-07T20:23:46', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '3aa67c7d-2ac6-42bd-bfc0-252e042b3b7b'	System	08 Sep 2020 00:24:04
User entered 'None (0)'	System	08 Sep 2020 00:24:04

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:26

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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-07T20:23:51', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '3aa67c7d-2ac6-42bd-bfc0-252e042b3b7b'	System	08 Sep 2020 00:24:04
User entered 'No (N)'	System	08 Sep 2020 00:24:04

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:26

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-07T20:24:01', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '3aa67c7d-2ac6-42bd-bfc0-252e042b3b7b'	System	08 Sep 2020 00:24:04
User entered '07 Sep 2020 20:24'	System	08 Sep 2020 00:24:04

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 18:08:00
User entered 'Day 6'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:26

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-08T21:29:28', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'c70bc20a-6995-4b1a-a820-2b05c508aff0'	System	09 Sep 2020 01:30:07
User entered 'None (0)'	System	09 Sep 2020 01:30:07

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:26

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-08T21:29:35', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'c70bc20a-6995-4b1a-a820-2b05c508aff0'	System	09 Sep 2020 01:30:07
User entered 'No interference with activity (1)'	System	09 Sep 2020 01:30:07

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-08T21:29:38', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'c70bc20a-6995-4b1a-a820-2b05c508aff0'	System	09 Sep 2020 01:30:07
User entered 'No interference with activity (1)'	System	09 Sep 2020 01:30:07

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-08T21:29:42', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'c70bc20a-6995-4b1a-a820-2b05c508aff0'	System	09 Sep 2020 01:30:07
User entered 'No interference with activity (1)'	System	09 Sep 2020 01:30:07

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-08T21:29:44', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'c70bc20a-6995-4b1a-a820-2b05c508aff0'	System	09 Sep 2020 01:30:07
User entered 'None (0)'	System	09 Sep 2020 01:30:07

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:26

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-08T21:29:47', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'c70bc20a-6995-4b1a-a820-2b05c508aff0'	System	09 Sep 2020 01:30:07
User entered 'None (0)'	System	09 Sep 2020 01:30:07

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:26

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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-08T21:29:55', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'c70bc20a-6995-4b1a-a820-2b05c508aff0'	System	09 Sep 2020 01:30:07
User entered 'No (N)'	System	09 Sep 2020 01:30:07

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:26

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-08T21:30:01', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'c70bc20a-6995-4b1a-a820-2b05c508aff0'	System	09 Sep 2020 01:30:07
User entered '08 Sep 2020 21:30'	System	09 Sep 2020 01:30:07

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 18:08:00
User entered 'Day 7'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:26

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-09T20:51:12', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '4ab5c654-8749-46a7-90a0-151663255594'	System	10 Sep 2020 00:51:44
User entered 'None (0)'	System	10 Sep 2020 00:51:44

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:26

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-09T20:51:17', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '4ab5c654-8749-46a7-90a0-151663255594'	System	10 Sep 2020 00:51:44
User entered 'None (0)'	System	10 Sep 2020 00:51:44

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-09T20:51:21', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '4ab5c654-8749-46a7-90a0-151663255594'	System	10 Sep 2020 00:51:44
User entered 'None (0)'	System	10 Sep 2020 00:51:44

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-09T20:51:28', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '4ab5c654-8749-46a7-90a0-151663255594'	System	10 Sep 2020 00:51:44
User entered 'None (0)'	System	10 Sep 2020 00:51:44

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-09T20:51:31', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '4ab5c654-8749-46a7-90a0-151663255594'	System	10 Sep 2020 00:51:44
User entered 'None (0)'	System	10 Sep 2020 00:51:44

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:26

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-09T20:51:34', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '4ab5c654-8749-46a7-90a0-151663255594'	System	10 Sep 2020 00:51:44
User entered 'None (0)'	System	10 Sep 2020 00:51:44

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:26

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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-09T20:51:37', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '4ab5c654-8749-46a7-90a0-151663255594'	System	10 Sep 2020 00:51:44
User entered 'No (N)'	System	10 Sep 2020 00:51:44

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:26

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-09T20:51:40', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '4ab5c654-8749-46a7-90a0-151663255594'	System	10 Sep 2020 00:51:44
User entered '09 Sep 2020 20:51'	System	10 Sep 2020 00:51:44

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 18:08:00

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(8)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Sep 2020 01:29:25
User entered 'Day 8'	System	09 Sep 2020 01:29:25

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(8)

Generated On: 26 Nov 2020 11:15:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-11T07:45:20', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '2cf730f5-b117-49c5-91f1-71f8b0a6b4b1'	System	11 Sep 2020 11:46:07
User entered 'Yes (Y)'	System	11 Sep 2020 11:46:07

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(8)

Generated On: 26 Nov 2020 11:15:26

Please record - REDNESS AT INJECTION SITE (in mm)

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-11T07:45:57', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '2cf730f5-b117-49c5-91f1-71f8b0a6b4b1' User entered '40'	System	11 Sep 2020 11:46:07
	System	11 Sep 2020 11:46:07

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(8)

Generated On: 26 Nov 2020 11:15:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-11T07:46:02', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '2cf730f5-b117-49c5-91f1-71f8b0a6b4b1'	System	11 Sep 2020 11:46:07
User entered '11 Sep 2020 07:46'	System	11 Sep 2020 11:46:07

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(8)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 01:29:25

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(8)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 01:29:25

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(9)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 00:51:08
User entered 'Day 9'	System	10 Sep 2020 00:51:08

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(9)

Generated On: 26 Nov 2020 11:15:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-11T20:06:50', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '0aa7554e-3f37-43d1-b57a-d5670998b09c'	System	12 Sep 2020 00:07:05
User entered 'Yes (Y)'	System	12 Sep 2020 00:07:05

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(9)

Generated On: 26 Nov 2020 11:15:26

Please record - REDNESS AT INJECTION SITE (in mm)

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-11T20:06:56', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '0aa7554e-3f37-43d1-b57a-d5670998b09c' User entered '110'	System	12 Sep 2020 00:07:05
	System	12 Sep 2020 00:07:05

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(9)

Generated On: 26 Nov 2020 11:15:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-11T20:07:01', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '0aa7554e-3f37-43d1-b57a-d5670998b09c'	System	12 Sep 2020 00:07:05
User entered '11 Sep 2020 20:07'	System	12 Sep 2020 00:07:05

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(9)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 00:51:08

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(9)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 00:51:08

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(10)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 11:46:07
User entered 'Day 10'	System	11 Sep 2020 11:46:07

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(10)

Generated On: 26 Nov 2020 11:15:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-12T19:52:29', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'c4403575-4b98-4226-ba0e-2b40125f3721'	System	12 Sep 2020 23:52:53
User entered 'Yes (Y)'	System	12 Sep 2020 23:52:53

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(10)

Generated On: 26 Nov 2020 11:15:26

Please record - REDNESS AT INJECTION SITE (in mm)

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-12T19:52:44', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'c4403575-4b98-4226-ba0e-2b40125f3721' User entered '110'	System	12 Sep 2020 23:52:53
	System	12 Sep 2020 23:52:53

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(10)

Generated On: 26 Nov 2020 11:15:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-12T19:52:50', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'c4403575-4b98-4226-ba0e-2b40125f3721'	System	12 Sep 2020 23:52:53
User entered '12 Sep 2020 19:52'	System	12 Sep 2020 23:52:53

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(10)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 11:46:07

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(10)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 11:46:07

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(11)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Sep 2020 00:07:05
User entered 'Day 11'	System	12 Sep 2020 00:07:05

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(11)

Generated On: 26 Nov 2020 11:15:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-13T18:24:35', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '6b84ad84-14f2-4a60-8452-29f78ce03951'	System	13 Sep 2020 22:24:55
User entered 'Yes (Y)'	System	13 Sep 2020 22:24:55

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(11)

Generated On: 26 Nov 2020 11:15:26

Please record - REDNESS AT INJECTION SITE (in mm)

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-13T18:24:45', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '6b84ad84-14f2-4a60-8452-29f78ce03951' User entered '150'	System	13 Sep 2020 22:24:55
	System	13 Sep 2020 22:24:55

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(11)

Generated On: 26 Nov 2020 11:15:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-13T18:24:49', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '6b84ad84-14f2-4a60-8452-29f78ce03951'	System	13 Sep 2020 22:24:55
User entered '13 Sep 2020 18:24'	System	13 Sep 2020 22:24:55

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(11)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	12 Sep 2020 00:07:05

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(11)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	12 Sep 2020 00:07:05

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(12)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Sep 2020 23:52:53
User entered 'Day 12'	System	12 Sep 2020 23:52:53

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(12)

Generated On: 26 Nov 2020 11:15:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-14T22:13:26', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '0ce56ef6-080d-431b-bc99-2c735da07837'	System	15 Sep 2020 02:13:46
User entered 'Yes (Y)'	System	15 Sep 2020 02:13:46

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(12)

Generated On: 26 Nov 2020 11:15:26

Please record - REDNESS AT INJECTION SITE (in mm)

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-14T22:13:39', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '0ce56ef6-080d-431b-bc99-2c735da07837' User entered '140'	System	15 Sep 2020 02:13:46
	System	15 Sep 2020 02:13:46

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(12)

Generated On: 26 Nov 2020 11:15:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-14T22:13:42', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '0ce56ef6-080d-431b-bc99-2c735da07837'	System	15 Sep 2020 02:13:46
User entered '14 Sep 2020 22:13'	System	15 Sep 2020 02:13:46

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(12)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	12 Sep 2020 23:52:53

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(12)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	12 Sep 2020 23:52:53

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(13)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Sep 2020 22:24:55
User entered 'Day 13'	System	13 Sep 2020 22:24:55

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(13)

Generated On: 26 Nov 2020 11:15:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-15T21:25:43', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '5ce76890-ef97-47a0-b661-ab32642b83da' User entered 'Yes (Y)'	System	16 Sep 2020 01:26:35
	System	16 Sep 2020 01:26:35

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(13)

Generated On: 26 Nov 2020 11:15:26

Please record - REDNESS AT INJECTION SITE (in mm)

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-15T21:25:49', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '5ce76890-ef97-47a0-b661-ab32642b83da' User entered '100'	System	16 Sep 2020 01:26:35
	System	16 Sep 2020 01:26:35

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(13)

Generated On: 26 Nov 2020 11:15:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-15T21:25:53', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '5ce76890-ef97-47a0-b661-ab32642b83da'	System	16 Sep 2020 01:26:35
User entered '15 Sep 2020 21:25'	System	16 Sep 2020 01:26:35

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(13)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	13 Sep 2020 22:24:55

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(13)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	13 Sep 2020 22:24:55

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(14)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 02:13:46
User entered 'Day 14'	System	15 Sep 2020 02:13:46

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(14)

Generated On: 26 Nov 2020 11:15:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-16T20:43:37', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'bffd9070-11d2-4989-9a5a-8f302cf3edcd'	System	17 Sep 2020 00:43:47
User entered 'Yes (Y)'	System	17 Sep 2020 00:43:47

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(14)

Generated On: 26 Nov 2020 11:15:26

Please record - REDNESS AT INJECTION SITE (in mm)

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-16T20:43:42', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'bffd9070-11d2-4989-9a5a-8f302cf3edcd' User entered '130'	System	17 Sep 2020 00:43:47
	System	17 Sep 2020 00:43:47

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(14)

Generated On: 26 Nov 2020 11:15:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-16T20:43:44', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'bffd9070-11d2-4989-9a5a-8f302cf3edcd'	System	17 Sep 2020 00:43:47
User entered '16 Sep 2020 20:43'	System	17 Sep 2020 00:43:47

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(14)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 02:13:46

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(14)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 02:13:46

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(15)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 01:26:35
User entered 'Day 15'	System	16 Sep 2020 01:26:35

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(15)

Generated On: 26 Nov 2020 11:15:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-17T12:12:03', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '11d3a7bb-967f-4b49-a8c0-ef9ef24fdb49'	System	17 Sep 2020 16:12:17
User entered 'Yes (Y)'	System	17 Sep 2020 16:12:17

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(15)

Generated On: 26 Nov 2020 11:15:26

Please record - REDNESS AT INJECTION SITE (in mm)

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-17T12:12:10', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '11d3a7bb-967f-4b49-a8c0-ef9ef24fdb49' User entered '130'	System	17 Sep 2020 16:12:17
	System	17 Sep 2020 16:12:17

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(15)

Generated On: 26 Nov 2020 11:15:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-17T12:12:13', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '11d3a7bb-967f-4b49-a8c0-ef9ef24fdb49'	System	17 Sep 2020 16:12:17
User entered '17 Sep 2020 12:12'	System	17 Sep 2020 16:12:17

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(15)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 01:26:35

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(15)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 01:26:35

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(16)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 00:43:47
User entered 'Day 16'	System	17 Sep 2020 00:43:47

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(16)

Generated On: 26 Nov 2020 11:15:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-18T20:27:03', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'cf3ac124-6f83-4d03-a965-9687da4689e9' User entered 'Yes (Y)'	System	19 Sep 2020 00:27:15
	System	19 Sep 2020 00:27:15

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(16)

Generated On: 26 Nov 2020 11:15:26

Please record - REDNESS AT INJECTION SITE (in mm)

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-18T20:27:08', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'cf3ac124-6f83-4d03-a965-9687da4689e9' User entered '130'	System	19 Sep 2020 00:27:15
	System	19 Sep 2020 00:27:15

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(16)

Generated On: 26 Nov 2020 11:15:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-18T20:27:13', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'cf3ac124-6f83-4d03-a965-9687da4689e9'	System	19 Sep 2020 00:27:15
User entered '18 Sep 2020 20:27'	System	19 Sep 2020 00:27:15

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(16)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 00:43:47

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(16)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 00:43:47

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(17)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 16:12:17
User entered 'Day 17'	System	17 Sep 2020 16:12:17

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(17)

Generated On: 26 Nov 2020 11:15:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-19T20:32:45', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'ca2ad44c-393d-4f5e-9aae-11b7c9d23fc2'	System	20 Sep 2020 00:32:59
User entered 'Yes (Y)'	System	20 Sep 2020 00:32:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(17)

Generated On: 26 Nov 2020 11:15:26

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

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-19T20:32:53', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'ca2ad44c-393d-4f5e-9aae-11b7c9d23fc2' User entered '95'	System	20 Sep 2020 00:32:59
	System	20 Sep 2020 00:32:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(17)

Generated On: 26 Nov 2020 11:15:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-19T20:32:57', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'ca2ad44c-393d-4f5e-9aae-11b7c9d23fc2'	System	20 Sep 2020 00:32:59
User entered '19 Sep 2020 20:32'	System	20 Sep 2020 00:32:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(17)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 16:12:17

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(17)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 16:12:17

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(18)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Sep 2020 00:27:15
User entered 'Day 18'	System	19 Sep 2020 00:27:15

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(18)

Generated On: 26 Nov 2020 11:15:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-21T07:22:32', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '06f6bc1c-72a9-4476-bf92-cbb8a87ebe23'	System	21 Sep 2020 11:22:44
User entered 'Yes (Y)'	System	21 Sep 2020 11:22:44

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(18)

Generated On: 26 Nov 2020 11:15:26

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

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-21T07:22:36', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '06f6bc1c-72a9-4476-bf92-cbb8a87ebe23' User entered '95'	System	21 Sep 2020 11:22:44
	System	21 Sep 2020 11:22:44

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(18)

Generated On: 26 Nov 2020 11:15:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-21T07:22:40', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '06f6bc1c-72a9-4476-bf92-cbb8a87ebe23' User entered '21 Sep 2020 07:22'	System	21 Sep 2020 11:22:44
	System	21 Sep 2020 11:22:44

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(18)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 12:00'	System	19 Sep 2020 00:27:15

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(18)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 11:59'	System	19 Sep 2020 00:27:15

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(19)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Sep 2020 00:32:59
User entered 'Day 19'	System	20 Sep 2020 00:32:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(19)

Generated On: 26 Nov 2020 11:15:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-22T00:24:35', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '8f42d2a7-d546-4bdb-a5c1-f3d21ec14f75'	System	22 Sep 2020 04:24:45
User entered 'Yes (Y)'	System	22 Sep 2020 04:24:45

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(19)

Generated On: 26 Nov 2020 11:15:26

Please record - REDNESS AT INJECTION SITE (in mm)

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-22T00:24:39', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '8f42d2a7-d546-4bdb-a5c1-f3d21ec14f75'	System	22 Sep 2020 04:24:45
User entered '90'	System	22 Sep 2020 04:24:45

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(19)

Generated On: 26 Nov 2020 11:15:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-22T00:24:42', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '8f42d2a7-d546-4bdb-a5c1-f3d21ec14f75'	System	22 Sep 2020 04:24:45
User entered '22 Sep 2020 00:24'	System	22 Sep 2020 04:24:45

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(19)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 12:00'	System	20 Sep 2020 00:32:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(19)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 11:59'	System	20 Sep 2020 00:32:59

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(20)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 11:22:44
User entered 'Day 20'	System	21 Sep 2020 11:22:44

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(20)

Generated On: 26 Nov 2020 11:15:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-23T02:14:10', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'e79d9fa7-c864-4a43-8087-44e0077f8929'	System	23 Sep 2020 06:14:20
User entered 'Yes (Y)'	System	23 Sep 2020 06:14:20

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(20)

Generated On: 26 Nov 2020 11:15:26

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

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-23T02:14:14', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'e79d9fa7-c864-4a43-8087-44e0077f8929' User entered '95'	System	23 Sep 2020 06:14:20
	System	23 Sep 2020 06:14:20

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(20)

Generated On: 26 Nov 2020 11:15:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-23T02:14:17', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'e79d9fa7-c864-4a43-8087-44e0077f8929' User entered '23 Sep 2020 02:14'	System	23 Sep 2020 06:14:20
	System	23 Sep 2020 06:14:20

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(20)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 11:22:44

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(20)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 11:22:44

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(21)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Sep 2020 04:24:45
User entered 'Day 21'	System	22 Sep 2020 04:24:45

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(21)

Generated On: 26 Nov 2020 11:15:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-23T23:43:30', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '3536a5a7-97cc-488e-a0b1-fa08cf4aef77'	System	24 Sep 2020 03:43:40
User entered 'Yes (Y)'	System	24 Sep 2020 03:43:40

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(21)

Generated On: 26 Nov 2020 11:15:26

Please record - REDNESS AT INJECTION SITE (in mm)

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-23T23:43:34', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '3536a5a7-97cc-488e-a0b1-fa08cf4aef77' User entered '80'	System	24 Sep 2020 03:43:40
	System	24 Sep 2020 03:43:40

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(21)

Generated On: 26 Nov 2020 11:15:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-23T23:43:37', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '3536a5a7-97cc-488e-a0b1-fa08cf4aef77'	System	24 Sep 2020 03:43:40
User entered '23 Sep 2020 23:43'	System	24 Sep 2020 03:43:40

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(21)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 04:24:45

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(21)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 04:24:45

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(22)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 06:14:20
User entered 'Day 22'	System	23 Sep 2020 06:14:20

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(22)

Generated On: 26 Nov 2020 11:15:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-24T18:23:34', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '48c0be3b-3fdd-4487-be97-24fbe17af0a6'	System	24 Sep 2020 22:23:42
User entered 'Yes (Y)'	System	24 Sep 2020 22:23:42

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(22)

Generated On: 26 Nov 2020 11:15:26

Please record - REDNESS AT INJECTION SITE (in mm)

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-24T18:23:37', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '48c0be3b-3fdd-4487-be97-24fbe17af0a6' User entered '80'	System	24 Sep 2020 22:23:42
	System	24 Sep 2020 22:23:42

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(22)

Generated On: 26 Nov 2020 11:15:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-24T18:23:40', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '48c0be3b-3fdd-4487-be97-24fbe17af0a6'	System	24 Sep 2020 22:23:42
User entered '24 Sep 2020 18:23'	System	24 Sep 2020 22:23:42

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(22)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 06:14:20

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(22)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 06:14:20

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(23)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Sep 2020 03:43:40
User entered 'Day 23'	System	24 Sep 2020 03:43:40

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(23)

Generated On: 26 Nov 2020 11:15:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-25T13:41:54', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'a70b4ad7-6440-47da-9706-5109ef2e93d4'	System	25 Sep 2020 17:42:05
User entered 'Yes (Y)'	System	25 Sep 2020 17:42:05

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(23)

Generated On: 26 Nov 2020 11:15:26

Please record - REDNESS AT INJECTION SITE (in mm)

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-25T13:41:58', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'a70b4ad7-6440-47da-9706-5109ef2e93d4' User entered '70'	System	25 Sep 2020 17:42:05
	System	25 Sep 2020 17:42:05

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(23)

Generated On: 26 Nov 2020 11:15:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-25T13:42:01', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'a70b4ad7-6440-47da-9706-5109ef2e93d4' User entered '25 Sep 2020 13:42'	System	25 Sep 2020 17:42:05
	System	25 Sep 2020 17:42:05

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(23)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 03:43:40

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(23)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 03:43:40

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(24)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Sep 2020 22:23:42
User entered 'Day 24'	System	24 Sep 2020 22:23:42

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(24)

Generated On: 26 Nov 2020 11:15:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-26T23:02:03', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'd2183ccb-2a6c-4b5e-8950-f9c822eed327'	System	27 Sep 2020 03:02:16
User entered 'Yes (Y)'	System	27 Sep 2020 03:02:16

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(24)

Generated On: 26 Nov 2020 11:15:26

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

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-26T23:02:08', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'd2183ccb-2a6c-4b5e-8950-f9c822eed327' User entered '70'	System	27 Sep 2020 03:02:16
	System	27 Sep 2020 03:02:16

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(24)

Generated On: 26 Nov 2020 11:15:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-26T23:02:11', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'd2183ccb-2a6c-4b5e-8950-f9c822eed327'	System	27 Sep 2020 03:02:16
User entered '26 Sep 2020 23:02'	System	27 Sep 2020 03:02:16

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(24)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 22:23:42

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(24)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 22:23:42

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(25)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Sep 2020 17:42:05
User entered 'Day 25'	System	25 Sep 2020 17:42:05

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(25)

Generated On: 26 Nov 2020 11:15:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-27T23:24:09', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'c347f892-81d2-4076-a1e0-ab5b0c559027'	System	28 Sep 2020 03:24:19
User entered 'Yes (Y)'	System	28 Sep 2020 03:24:19

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(25)

Generated On: 26 Nov 2020 11:15:26

Please record - REDNESS AT INJECTION SITE (in mm)

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-27T23:24:13', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'c347f892-81d2-4076-a1e0-ab5b0c559027' User entered '75'	System	28 Sep 2020 03:24:19
	System	28 Sep 2020 03:24:19

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(25)

Generated On: 26 Nov 2020 11:15:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-27T23:24:16', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'c347f892-81d2-4076-a1e0-ab5b0c559027'	System	28 Sep 2020 03:24:19
User entered '27 Sep 2020 23:24'	System	28 Sep 2020 03:24:19

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(25)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 17:42:05

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(25)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 17:42:05

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(26)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Sep 2020 03:02:16
User entered 'Day 26'	System	27 Sep 2020 03:02:16

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(26)

Generated On: 26 Nov 2020 11:15:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-28T21:53:31', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'd8d627b8-6e57-4ee6-a498-42ce44de39e8' User entered 'Yes (Y)'	System	29 Sep 2020 01:53:44
	System	29 Sep 2020 01:53:44

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(26)

Generated On: 26 Nov 2020 11:15:26

Please record - REDNESS AT INJECTION SITE (in mm)

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-28T21:53:39', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'd8d627b8-6e57-4ee6-a498-42ce44de39e8' User entered '70'	System	29 Sep 2020 01:53:44
	System	29 Sep 2020 01:53:44

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(26)

Generated On: 26 Nov 2020 11:15:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-28T21:53:42', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'd8d627b8-6e57-4ee6-a498-42ce44de39e8'	System	29 Sep 2020 01:53:44
User entered '28 Sep 2020 21:53'	System	29 Sep 2020 01:53:44

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(26)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 12:00'	System	27 Sep 2020 03:02:16

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(26)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 11:59'	System	27 Sep 2020 03:02:16

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(27)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Sep 2020 03:24:19
User entered 'Day 27'	System	28 Sep 2020 03:24:19

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(27)

Generated On: 26 Nov 2020 11:15:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-29T12:13:23', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '39b533c1-d2b8-43df-9cc4-839d966679b6'	System	29 Sep 2020 16:13:36
User entered 'Yes (Y)'	System	29 Sep 2020 16:13:36

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(27)

Generated On: 26 Nov 2020 11:15:26

Please record - REDNESS AT INJECTION SITE (in mm)

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-29T12:13:27', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '39b533c1-d2b8-43df-9cc4-839d966679b6' User entered '70'	System	29 Sep 2020 16:13:36
	System	29 Sep 2020 16:13:36

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(27)

Generated On: 26 Nov 2020 11:15:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-29T12:13:30', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '39b533c1-d2b8-43df-9cc4-839d966679b6'	System	29 Sep 2020 16:13:36
User entered '29 Sep 2020 12:13'	System	29 Sep 2020 16:13:36

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(27)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 03:24:19

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(27)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 03:24:19

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(28)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 01:53:44
User entered 'Day 28'	System	29 Sep 2020 01:53:44

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(28)

Generated On: 26 Nov 2020 11:15:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-30T22:43:28', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '8b9a74d4-d686-49c5-ab1a-dc67450c134d'	System	01 Oct 2020 02:43:37
User entered 'Yes (Y)'	System	01 Oct 2020 02:43:37

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(28)

Generated On: 26 Nov 2020 11:15:26

Please record - REDNESS AT INJECTION SITE (in mm)

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-30T22:43:32', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '8b9a74d4-d686-49c5-ab1a-dc67450c134d' User entered '70'	System	01 Oct 2020 02:43:37
	System	01 Oct 2020 02:43:37

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(28)

Generated On: 26 Nov 2020 11:15:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-30T22:43:35', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '8b9a74d4-d686-49c5-ab1a-dc67450c134d' User entered '30 Sep 2020 22:43'	System	01 Oct 2020 02:43:37
	System	01 Oct 2020 02:43:37

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(28)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 01:53:44

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(28)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 01:53:44

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(29)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 16:13:36
User entered 'Day 29'	System	29 Sep 2020 16:13:36

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(29)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 16:13:36

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(29)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 16:13:36

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(30)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 02:43:37
User entered 'Day 30'	System	01 Oct 2020 02:43:37

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(30)

Generated On: 26 Nov 2020 11:15:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-02T20:42:19', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'b683db76-04b6-4197-a16c-f88bf98e6887'	System	03 Oct 2020 00:42:31
User entered 'Yes (Y)'	System	03 Oct 2020 00:42:31

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(30)

Generated On: 26 Nov 2020 11:15:26

Please record - REDNESS AT INJECTION SITE (in mm)

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-02T20:42:22', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'b683db76-04b6-4197-a16c-f88bf98e6887' User entered '80'	System	03 Oct 2020 00:42:31
	System	03 Oct 2020 00:42:31

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(30)

Generated On: 26 Nov 2020 11:15:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-02T20:42:25', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'b683db76-04b6-4197-a16c-f88bf98e6887'	System	03 Oct 2020 00:42:31
User entered '02 Oct 2020 20:42'	System	03 Oct 2020 00:42:31

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(30)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 02:43:37

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(30)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 02:43:37

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(31)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Oct 2020 00:42:31
User entered 'Day 31'	System	03 Oct 2020 00:42:31

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(31)

Generated On: 26 Nov 2020 11:15:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-03T21:22:31', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'ea17fbd2-d25d-4393-af92-88e9719c5314'	System	04 Oct 2020 01:22:42
User entered 'Yes (Y)'	System	04 Oct 2020 01:22:42

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(31)

Generated On: 26 Nov 2020 11:15:26

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

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-03T21:22:36', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'ea17fbd2-d25d-4393-af92-88e9719c5314' User entered '80'	System	04 Oct 2020 01:22:42
	System	04 Oct 2020 01:22:42

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(31)

Generated On: 26 Nov 2020 11:15:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-03T21:22:38', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'ea17fbd2-d25d-4393-af92-88e9719c5314'	System	04 Oct 2020 01:22:42
User entered '03 Oct 2020 21:22'	System	04 Oct 2020 01:22:42

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(31)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 12:00'	System	03 Oct 2020 00:42:31

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(31)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 11:59'	System	03 Oct 2020 00:42:31

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(32)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Oct 2020 00:42:31
User entered 'Day 32'	System	03 Oct 2020 00:42:31

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(32)

Generated On: 26 Nov 2020 11:15:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-05T08:58:57', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'cb314901-fd0d-4d0f-90d6-9e971c1a4da5'	System	05 Oct 2020 12:59:08
User entered 'Yes (Y)'	System	05 Oct 2020 12:59:08

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(32)

Generated On: 26 Nov 2020 11:15:26

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

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-05T08:59:04', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'cb314901-fd0d-4d0f-90d6-9e971c1a4da5' User entered '70'	System	05 Oct 2020 12:59:08
	System	05 Oct 2020 12:59:08

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(32)

Generated On: 26 Nov 2020 11:15:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-05T08:59:07', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'cb314901-fd0d-4d0f-90d6-9e971c1a4da5'	System	05 Oct 2020 12:59:08
User entered '05 Oct 2020 08:59'	System	05 Oct 2020 12:59:08

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(32)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 12:00'	System	03 Oct 2020 00:42:31

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(32)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 11:59'	System	03 Oct 2020 00:42:31

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(33)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Oct 2020 01:22:42
User entered 'Day 33'	System	04 Oct 2020 01:22:42

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(33)

Generated On: 26 Nov 2020 11:15:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-05T14:19:13', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '9855626c-c501-4c7e-b9eb-66837e428737'	System	05 Oct 2020 18:19:28
User entered 'Yes (Y)'	System	05 Oct 2020 18:19:28

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(33)

Generated On: 26 Nov 2020 11:15:26

Please record - REDNESS AT INJECTION SITE (in mm)

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-05T14:19:17', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '9855626c-c501-4c7e-b9eb-66837e428737' User entered '70'	System	05 Oct 2020 18:19:28
	System	05 Oct 2020 18:19:28

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(33)

Generated On: 26 Nov 2020 11:15:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-05T14:19:23', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '9855626c-c501-4c7e-b9eb-66837e428737'	System	05 Oct 2020 18:19:28
User entered '05 Oct 2020 14:19'	System	05 Oct 2020 18:19:28

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(33)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 12:00'	System	04 Oct 2020 01:22:42

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(33)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 11:59'	System	04 Oct 2020 01:22:42

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(34)

Generated On: 26 Nov 2020 11:15:26

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	05 Oct 2020 12:59:08
User entered 'Day 34'	System	05 Oct 2020 12:59:08

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(34)

Generated On: 26 Nov 2020 11:15:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-06T19:32:40', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '80464290-40bd-44c9-94c7-74d4f6b965aa'	System	06 Oct 2020 23:32:50
User entered 'Yes (Y)'	System	06 Oct 2020 23:32:50

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(34)

Generated On: 26 Nov 2020 11:15:26

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

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-06T19:32:43', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '80464290-40bd-44c9-94c7-74d4f6b965aa' User entered '70'	System	06 Oct 2020 23:32:50
	System	06 Oct 2020 23:32:50

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(34)

Generated On: 26 Nov 2020 11:15:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-06T19:32:46', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '80464290-40bd-44c9-94c7-74d4f6b965aa'	System	06 Oct 2020 23:32:50
User entered '06 Oct 2020 19:32'	System	06 Oct 2020 23:32:50

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(34)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 12:00'	System	05 Oct 2020 12:59:08

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(34)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 11:59'	System	05 Oct 2020 12:59:08

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(35)

Generated On: 26 Nov 2020 11:15:26

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	05 Oct 2020 18:19:28
User entered 'Day 35'	System	05 Oct 2020 18:19:28

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(35)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-07T19:22:50', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '9f2389d1-4943-45b3-90ef-8b13baef6141'	System	07 Oct 2020 23:23:01
User entered 'Yes (Y)'	System	07 Oct 2020 23:23:01

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(35)

Generated On: 26 Nov 2020 11:15:26

Please record - REDNESS AT INJECTION SITE (in mm)

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-07T19:22:54', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '9f2389d1-4943-45b3-90ef-8b13baef6141' User entered '70'	System	07 Oct 2020 23:23:01
	System	07 Oct 2020 23:23:01

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(35)

Generated On: 26 Nov 2020 11:15:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-07T19:22:56', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '9f2389d1-4943-45b3-90ef-8b13baef6141'	System	07 Oct 2020 23:23:01
User entered '07 Oct 2020 19:22'	System	07 Oct 2020 23:23:01

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(35)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 12:00'	System	05 Oct 2020 18:19:28

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(35)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 11:59'	System	05 Oct 2020 18:19:28

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(36)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Oct 2020 23:32:50
User entered 'Day 36'	System	06 Oct 2020 23:32:50

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(36)

Generated On: 26 Nov 2020 11:15:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-09T00:40:23', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '373253f4-681c-4a3a-a0b8-49ca3187fbf3'	System	09 Oct 2020 04:40:34
User entered 'Yes (Y)'	System	09 Oct 2020 04:40:34

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(36)

Generated On: 26 Nov 2020 11:15:26

Please record - REDNESS AT INJECTION SITE (in mm)

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-09T00:40:27', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '373253f4-681c-4a3a-a0b8-49ca3187fbf3' User entered '50'	System	09 Oct 2020 04:40:34

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(36)

Generated On: 26 Nov 2020 11:15:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-09T00:40:30', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '373253f4-681c-4a3a-a0b8-49ca3187fbf3'	System	09 Oct 2020 04:40:34
User entered '09 Oct 2020 00:40'	System	09 Oct 2020 04:40:34

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(36)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 23:32:50

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(36)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 23:32:50

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(37)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 23:23:01
User entered 'Day 37'	System	07 Oct 2020 23:23:01

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(37)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-09T22:52:51', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '38d50110-0408-4abc-aaac-32fdcffa32ef'	System	10 Oct 2020 02:53:02
User entered 'Yes (Y)'	System	10 Oct 2020 02:53:02

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(37)

Generated On: 26 Nov 2020 11:15:26

Please record - REDNESS AT INJECTION SITE (in mm)

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-09T22:52:55', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '38d50110-0408-4abc-aaac-32fdcffa32ef' User entered '40'	System	10 Oct 2020 02:53:02
	System	10 Oct 2020 02:53:02

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(37)

Generated On: 26 Nov 2020 11:15:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-09T22:52:57', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '38d50110-0408-4abc-aaac-32fdcffa32ef' User entered '09 Oct 2020 22:52'	System	10 Oct 2020 02:53:02
	System	10 Oct 2020 02:53:02

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(37)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 23:23:01

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(37)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 23:23:01

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(38)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Oct 2020 04:40:34
User entered 'Day 38'	System	09 Oct 2020 04:40:34

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(38)

Generated On: 26 Nov 2020 11:15:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-11T07:18:41', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '40c62073-aae0-4916-aa9b-415a939f69a0'	System	11 Oct 2020 11:18:49
User entered 'No (N)'	System	11 Oct 2020 11:18:49

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(38)

Generated On: 26 Nov 2020 11:15:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-11T07:18:46', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '40c62073-aae0-4916-aa9b-415a939f69a0' User entered '11 Oct 2020 07:18'	System	11 Oct 2020 11:18:49
	System	11 Oct 2020 11:18:49

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(38)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 04:40:34

US3762177

Folder: Diary Dose 1 (1)

Form: Redness_Day(38)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 04:40:34

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Sep 2020 01:29:25
User entered 'Day 8'	System	09 Sep 2020 01:29:25

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:15:26

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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-11T07:46:08', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '1ab0c648-0870-4c2b-832b-37a38bd77b65'	System	11 Sep 2020 11:46:13
User entered 'No (N)'	System	11 Sep 2020 11:46:13

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:15:26

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-11T07:46:11', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '1ab0c648-0870-4c2b-832b-37a38bd77b65'	System	11 Sep 2020 11:46:13
User entered '11 Sep 2020 07:46'	System	11 Sep 2020 11:46:13

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 01:29:25

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 01:29:25

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 00:51:08
User entered 'Day 9'	System	10 Sep 2020 00:51:08

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 11:15:26

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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-11T20:07:06', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '9f6a452b-6903-4e9a-ad85-dc3dc6dc0de0'	System	12 Sep 2020 00:07:17
User entered 'No (N)'	System	12 Sep 2020 00:07:17

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 11:15:26

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-11T20:07:09', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '9f6a452b-6903-4e9a-ad85-dc3dc6dc0de0'	System	12 Sep 2020 00:07:17
User entered '11 Sep 2020 20:07'	System	12 Sep 2020 00:07:17

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 00:51:08

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 00:51:08

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Sep 2020 11:46:07
User entered 'Day 10'	System	11 Sep 2020 11:46:07

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 11:15:26

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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-12T19:52:54', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '9f8e0bae-3d6c-400f-a877-6ade263139a8'	System	12 Sep 2020 23:52:59
User entered 'No (N)'	System	12 Sep 2020 23:52:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 11:15:26

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-12T19:52:57', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '9f8e0bae-3d6c-400f-a877-6ade263139a8'	System	12 Sep 2020 23:52:59
User entered '12 Sep 2020 19:52'	System	12 Sep 2020 23:52:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 11:46:07

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 11:46:07

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Sep 2020 00:07:05
User entered 'Day 11'	System	12 Sep 2020 00:07:05

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 11:15:26

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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-13T18:24:54', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '0eef9eb6-172b-40d1-ab98-5ad2fdc47a3c'	System	13 Sep 2020 22:25:02
User entered 'No (N)'	System	13 Sep 2020 22:25:02

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 11:15:26

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-13T18:24:58', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '0eef9eb6-172b-40d1-ab98-5ad2fdc47a3c'	System	13 Sep 2020 22:25:02
User entered '13 Sep 2020 18:24'	System	13 Sep 2020 22:25:02

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	12 Sep 2020 00:07:05

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	12 Sep 2020 00:07:05

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Sep 2020 23:52:53
User entered 'Day 12'	System	12 Sep 2020 23:52:53

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 11:15:26

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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-14T22:13:46', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'f66890d5-0ea9-4053-a16b-892be3f66b7a'	System	15 Sep 2020 02:13:52
User entered 'No (N)'	System	15 Sep 2020 02:13:52

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 11:15:26

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-14T22:13:51', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'f66890d5-0ea9-4053-a16b-892be3f66b7a'	System	15 Sep 2020 02:13:52
User entered '14 Sep 2020 22:13'	System	15 Sep 2020 02:13:52

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	12 Sep 2020 23:52:53

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	12 Sep 2020 23:52:53

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Sep 2020 22:24:55
User entered 'Day 13'	System	13 Sep 2020 22:24:55

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 11:15:26

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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-15T21:25:57', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'f8b6a8a4-ab78-4cd9-896d-96503f0770ae'	System	16 Sep 2020 01:26:36
User entered 'No (N)'	System	16 Sep 2020 01:26:36

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 11:15:26

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-15T21:26:00', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'f8b6a8a4-ab78-4cd9-896d-96503f0770ae'	System	16 Sep 2020 01:26:36
User entered '15 Sep 2020 21:26'	System	16 Sep 2020 01:26:36

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	13 Sep 2020 22:24:55

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	13 Sep 2020 22:24:55

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 02:13:46
User entered 'Day 14'	System	15 Sep 2020 02:13:46

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 11:15:26

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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-16T20:43:48', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '49337e90-c55d-410c-8a9c-d854dbf45fc9'	System	17 Sep 2020 00:43:53
User entered 'No (N)'	System	17 Sep 2020 00:43:53

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 11:15:26

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-16T20:43:51', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '49337e90-c55d-410c-8a9c-d854dbf45fc9'	System	17 Sep 2020 00:43:53
User entered '16 Sep 2020 20:43'	System	17 Sep 2020 00:43:53

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 02:13:46

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 02:13:46

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 01:26:35
User entered 'Day 15'	System	16 Sep 2020 01:26:35

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 11:15:26

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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-17T12:12:19', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '94fa559e-0cc1-468c-8d37-ed2e5022609f'	System	17 Sep 2020 16:12:27
User entered 'No (N)'	System	17 Sep 2020 16:12:27

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 11:15:26

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-17T12:12:22', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '94fa559e-0cc1-468c-8d37-ed2e5022609f' User entered '17 Sep 2020 12:12'	System	17 Sep 2020 16:12:27
	System	17 Sep 2020 16:12:27

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 01:26:35

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 01:26:35

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 00:43:47
User entered 'Day 16'	System	17 Sep 2020 00:43:47

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 26 Nov 2020 11:15:26

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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-18T20:27:25', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '33e2e4d9-05d4-4554-a314-f53b8e1446b8'	System	19 Sep 2020 00:27:32
User entered 'Yes (Y)'	System	19 Sep 2020 00:27:32

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 26 Nov 2020 11:15:26

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-18T20:27:30', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '33e2e4d9-05d4-4554-a314-f53b8e1446b8'	System	19 Sep 2020 00:27:32
User entered '18 Sep 2020 20:27'	System	19 Sep 2020 00:27:32

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 00:43:47

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 00:43:47

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 16:12:17
User entered 'Day 17'	System	17 Sep 2020 16:12:17

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 26 Nov 2020 11:15:26

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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-19T20:33:05', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'af3692d8-3509-46a3-b1f2-ac06487afe7b'	System	20 Sep 2020 00:33:10
User entered 'No (N)'	System	20 Sep 2020 00:33:10

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 26 Nov 2020 11:15:26

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-19T20:33:09', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'af3692d8-3509-46a3-b1f2-ac06487afe7b'	System	20 Sep 2020 00:33:10
User entered '19 Sep 2020 20:33'	System	20 Sep 2020 00:33:10

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 16:12:17

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 16:12:17

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Sep 2020 00:27:15
User entered 'Day 18'	System	19 Sep 2020 00:27:15

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 26 Nov 2020 11:15:26

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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-21T07:22:48', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'efb45064-ddd0-46e3-9925-a257ce5f6506'	System	21 Sep 2020 11:22:52
User entered 'No (N)'	System	21 Sep 2020 11:22:52

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 26 Nov 2020 11:15:26

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-21T07:22:51', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'efb45064-ddd0-46e3-9925-a257ce5f6506'	System	21 Sep 2020 11:22:52
User entered '21 Sep 2020 07:22'	System	21 Sep 2020 11:22:52

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 12:00'	System	19 Sep 2020 00:27:15

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 11:59'	System	19 Sep 2020 00:27:15

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Sep 2020 00:32:59
User entered 'Day 19'	System	20 Sep 2020 00:32:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 26 Nov 2020 11:15:26

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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-22T00:24:46', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '1ecdcd5-7454-44e8-8278-3b346ab39fc6'	System	22 Sep 2020 04:24:51
User entered 'No (N)'	System	22 Sep 2020 04:24:51

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 26 Nov 2020 11:15:26

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-22T00:24:49', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '1ecdcd5-7454-44e8-8278-3b346ab39fc6'	System	22 Sep 2020 04:24:51
User entered '22 Sep 2020 00:24'	System	22 Sep 2020 04:24:51

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 12:00'	System	20 Sep 2020 00:32:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 11:59'	System	20 Sep 2020 00:32:59

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 11:22:44
User entered 'Day 20'	System	21 Sep 2020 11:22:44

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 26 Nov 2020 11:15:26

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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-23T02:14:21', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '67e72831-8509-466b-99b2-5e51a79f234d'	System	23 Sep 2020 06:14:26
User entered 'No (N)'	System	23 Sep 2020 06:14:26

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 26 Nov 2020 11:15:26

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-23T02:14:25', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '67e72831-8509-466b-99b2-5e51a79f234d'	System	23 Sep 2020 06:14:26
User entered '23 Sep 2020 02:14'	System	23 Sep 2020 06:14:26

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 11:22:44

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 11:22:44

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Sep 2020 04:24:45
User entered 'Day 21'	System	22 Sep 2020 04:24:45

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 26 Nov 2020 11:15:26

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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-23T23:43:42', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '28790100-b6ce-4e7b-8159-7ed3692466df'	System	24 Sep 2020 03:43:53
User entered 'No (N)'	System	24 Sep 2020 03:43:53

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 26 Nov 2020 11:15:26

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-23T23:43:48', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '28790100-b6ce-4e7b-8159-7ed3692466df' User entered '23 Sep 2020 23:43'	System	24 Sep 2020 03:43:53
	System	24 Sep 2020 03:43:53

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 04:24:45

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 04:24:45

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 06:14:20
User entered 'Day 22'	System	23 Sep 2020 06:14:20

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 26 Nov 2020 11:15:26

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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-24T18:23:44', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '0e9f3e37-46cf-444e-80f6-606a2d55f0c8'	System	24 Sep 2020 22:23:50
User entered 'No (N)'	System	24 Sep 2020 22:23:50

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 26 Nov 2020 11:15:26

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-24T18:23:47', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '0e9f3e37-46cf-444e-80f6-606a2d55f0c8'	System	24 Sep 2020 22:23:50
User entered '24 Sep 2020 18:23'	System	24 Sep 2020 22:23:50

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 06:14:20

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 06:14:20

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Sep 2020 03:43:40
User entered 'Day 23'	System	24 Sep 2020 03:43:40

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 26 Nov 2020 11:15:26

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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-25T13:42:05', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'cc0cbff1-97d0-429b-bab6-5e478ffe5ca8'	System	25 Sep 2020 17:42:11
User entered 'No (N)'	System	25 Sep 2020 17:42:11

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 26 Nov 2020 11:15:26

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-25T13:42:08', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'cc0cbff1-97d0-429b-bab6-5e478ffe5ca8'	System	25 Sep 2020 17:42:11
User entered '25 Sep 2020 13:42'	System	25 Sep 2020 17:42:11

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 03:43:40

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 03:43:40

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Sep 2020 22:23:42
User entered 'Day 24'	System	24 Sep 2020 22:23:42

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 26 Nov 2020 11:15:26

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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-26T23:02:15', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'ed3e8d9b-63bd-45cf-a865-b139994594c4'	System	27 Sep 2020 03:02:21
User entered 'No (N)'	System	27 Sep 2020 03:02:21

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 26 Nov 2020 11:15:26

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-26T23:02:17', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'ed3e8d9b-63bd-45cf-a865-b139994594c4'	System	27 Sep 2020 03:02:21
User entered '26 Sep 2020 23:02'	System	27 Sep 2020 03:02:21

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 22:23:42

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 22:23:42

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Sep 2020 17:42:05
User entered 'Day 25'	System	25 Sep 2020 17:42:05

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 26 Nov 2020 11:15:26

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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-27T23:24:22', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '1882171e-3006-4a7f-9b26-d3a2bf2d8fd6'	System	28 Sep 2020 03:24:29
User entered 'No (N)'	System	28 Sep 2020 03:24:29

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 26 Nov 2020 11:15:26

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-27T23:24:25', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '1882171e-3006-4a7f-9b26-d3a2bf2d8fd6'	System	28 Sep 2020 03:24:29
User entered '27 Sep 2020 23:24'	System	28 Sep 2020 03:24:29

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 17:42:05

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 17:42:05

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Sep 2020 03:02:16
User entered 'Day 26'	System	27 Sep 2020 03:02:16

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 26 Nov 2020 11:15:26

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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-28T21:53:46', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'a1010553-721a-4437-b737-b68b3f5d6f3c'	System	29 Sep 2020 01:53:52
User entered 'No (N)'	System	29 Sep 2020 01:53:52

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 26 Nov 2020 11:15:26

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-28T21:53:49', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'a1010553-721a-4437-b737-b68b3f5d6f3c'	System	29 Sep 2020 01:53:52
User entered '28 Sep 2020 21:53'	System	29 Sep 2020 01:53:52

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 12:00'	System	27 Sep 2020 03:02:16

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 11:59'	System	27 Sep 2020 03:02:16

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Sep 2020 03:24:19
User entered 'Day 27'	System	28 Sep 2020 03:24:19

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 26 Nov 2020 11:15:26

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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-29T12:13:34', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '829bd62b-2039-4d4b-9862-c8e622dfe8cb'	System	29 Sep 2020 16:13:39
User entered 'No (N)'	System	29 Sep 2020 16:13:39

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 26 Nov 2020 11:15:26

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-29T12:13:37', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '829bd62b-2039-4d4b-9862-c8e622dfe8cb'	System	29 Sep 2020 16:13:39
User entered '29 Sep 2020 12:13'	System	29 Sep 2020 16:13:39

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 03:24:19

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 03:24:19

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(28)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 01:53:44
User entered 'Day 28'	System	29 Sep 2020 01:53:44

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(28)

Generated On: 26 Nov 2020 11:15:26

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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-30T22:43:39', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '2b485b4d-34c5-422a-85b0-9d211010e91f'	System	01 Oct 2020 02:43:46
User entered 'No (N)'	System	01 Oct 2020 02:43:46

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(28)

Generated On: 26 Nov 2020 11:15:26

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-09-30T22:43:44', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '2b485b4d-34c5-422a-85b0-9d211010e91f'	System	01 Oct 2020 02:43:46
User entered '30 Sep 2020 22:43'	System	01 Oct 2020 02:43:46

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(28)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 01:53:44

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(28)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 01:53:44

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 16:13:36
User entered 'Day 29'	System	29 Sep 2020 16:13:36

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 16:13:36

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 16:13:36

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(30)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 02:43:37
User entered 'Day 30'	System	01 Oct 2020 02:43:37

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(30)

Generated On: 26 Nov 2020 11:15:26

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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-02T20:42:32', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'df083d42-32f6-42fa-825a-6d7f39ab2ae1'	System	03 Oct 2020 00:42:38
User entered 'No (N)'	System	03 Oct 2020 00:42:38

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(30)

Generated On: 26 Nov 2020 11:15:26

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-02T20:42:35', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'df083d42-32f6-42fa-825a-6d7f39ab2ae1'	System	03 Oct 2020 00:42:38
User entered '02 Oct 2020 20:42'	System	03 Oct 2020 00:42:38

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(30)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 02:43:37

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(30)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 02:43:37

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(31)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Oct 2020 00:42:31
User entered 'Day 31'	System	03 Oct 2020 00:42:31

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(31)

Generated On: 26 Nov 2020 11:15:26

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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-03T21:22:45', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '5ad87883-c7cd-4c7e-b196-a22afc64b880'	System	04 Oct 2020 01:22:50
User entered 'No (N)'	System	04 Oct 2020 01:22:50

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(31)

Generated On: 26 Nov 2020 11:15:26

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-03T21:22:48', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '5ad87883-c7cd-4c7e-b196-a22afc64b880'	System	04 Oct 2020 01:22:50
User entered '03 Oct 2020 21:22'	System	04 Oct 2020 01:22:50

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(31)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 12:00'	System	03 Oct 2020 00:42:31

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(31)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 11:59'	System	03 Oct 2020 00:42:31

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(32)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Oct 2020 00:42:31
User entered 'Day 32'	System	03 Oct 2020 00:42:31

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(32)

Generated On: 26 Nov 2020 11:15:26

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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-05T08:59:12', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '3dd75af2-1ada-4765-a4ae-609d1e868b84'	System	05 Oct 2020 12:59:20
User entered 'No (N)'	System	05 Oct 2020 12:59:20

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(32)

Generated On: 26 Nov 2020 11:15:26

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-05T08:59:14', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '3dd75af2-1ada-4765-a4ae-609d1e868b84'	System	05 Oct 2020 12:59:20
User entered '05 Oct 2020 08:59'	System	05 Oct 2020 12:59:20

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(32)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 12:00'	System	03 Oct 2020 00:42:31

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(32)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 11:59'	System	03 Oct 2020 00:42:31

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(33)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Oct 2020 01:22:42
User entered 'Day 33'	System	04 Oct 2020 01:22:42

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(33)

Generated On: 26 Nov 2020 11:15:26

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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-05T14:19:27', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '0daeb8e5-04cc-4977-8101-7ffd8572199e'	System	05 Oct 2020 18:19:34
User entered 'No (N)'	System	05 Oct 2020 18:19:34

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(33)

Generated On: 26 Nov 2020 11:15:26

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-05T14:19:30', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '0daeb8e5-04cc-4977-8101-7ffd8572199e'	System	05 Oct 2020 18:19:34
User entered '05 Oct 2020 14:19'	System	05 Oct 2020 18:19:34

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(33)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 12:00'	System	04 Oct 2020 01:22:42

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(33)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 11:59'	System	04 Oct 2020 01:22:42

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(34)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Oct 2020 12:59:08
User entered 'Day 34'	System	05 Oct 2020 12:59:08

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(34)

Generated On: 26 Nov 2020 11:15:26

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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-06T19:32:52', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '32874508-beec-4a7c-8afe-9576e32b3c09'	System	06 Oct 2020 23:32:57
User entered 'No (N)'	System	06 Oct 2020 23:32:57

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(34)

Generated On: 26 Nov 2020 11:15:26

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-06T19:32:55', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '32874508-beec-4a7c-8afe-9576e32b3c09' User entered '06 Oct 2020 19:32'	System	06 Oct 2020 23:32:57
	System	06 Oct 2020 23:32:57

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(34)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 12:00'	System	05 Oct 2020 12:59:08

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(34)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 11:59'	System	05 Oct 2020 12:59:08

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(35)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Oct 2020 18:19:28
User entered 'Day 35'	System	05 Oct 2020 18:19:28

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(35)

Generated On: 26 Nov 2020 11:15:26

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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-07T19:23:03', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'bd819cb5-6c03-4d73-a104-e364c75ebc43'	System	07 Oct 2020 23:23:08
User entered 'No (N)'	System	07 Oct 2020 23:23:08

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(35)

Generated On: 26 Nov 2020 11:15:26

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-07T19:23:06', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'bd819cb5-6c03-4d73-a104-e364c75ebc43'	System	07 Oct 2020 23:23:08
User entered '07 Oct 2020 19:23'	System	07 Oct 2020 23:23:08

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(35)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 12:00'	System	05 Oct 2020 18:19:28

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(35)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 11:59'	System	05 Oct 2020 18:19:28

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(36)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Oct 2020 23:32:50
User entered 'Day 36'	System	06 Oct 2020 23:32:50

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(36)

Generated On: 26 Nov 2020 11:15:26

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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-09T00:40:34', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '664c5b9d-06c6-4487-94b7-ca0aa74572f5'	System	09 Oct 2020 04:40:38
User entered 'No (N)'	System	09 Oct 2020 04:40:38

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(36)

Generated On: 26 Nov 2020 11:15:26

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-09T00:40:36', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '664c5b9d-06c6-4487-94b7-ca0aa74572f5' User entered '09 Oct 2020 00:40'	System	09 Oct 2020 04:40:38
	System	09 Oct 2020 04:40:38

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(36)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 23:32:50

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(36)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 23:32:50

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(37)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 23:23:01
User entered 'Day 37'	System	07 Oct 2020 23:23:01

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(37)

Generated On: 26 Nov 2020 11:15:26

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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-09T22:53:03', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'd28f5600-091a-42c3-8ae4-9e0abec4f4af'	System	10 Oct 2020 02:53:10
User entered 'No (N)'	System	10 Oct 2020 02:53:10

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(37)

Generated On: 26 Nov 2020 11:15:26

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-09T22:53:06', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'd28f5600-091a-42c3-8ae4-9e0abec4f4af' User entered '09 Oct 2020 22:53'	System	10 Oct 2020 02:53:10
	System	10 Oct 2020 02:53:10

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(37)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 23:23:01

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(37)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 23:23:01

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(38)

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Oct 2020 04:40:34
User entered 'Day 38'	System	09 Oct 2020 04:40:34

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(38)

Generated On: 26 Nov 2020 11:15:26

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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-11T07:18:51', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'a78d3e51-8595-4d3c-a286-a4d916f90a29'	System	11 Oct 2020 11:18:58
User entered 'No (N)'	System	11 Oct 2020 11:18:58

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(38)

Generated On: 26 Nov 2020 11:15:26

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-10-11T07:18:54', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'a78d3e51-8595-4d3c-a286-a4d916f90a29' User entered '11 Oct 2020 07:18'	System	11 Oct 2020 11:18:58
	System	11 Oct 2020 11:18:58

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(38)

Generated On: 26 Nov 2020 11:15:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 04:40:34

US3762177

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(38)

Generated On: 26 Nov 2020 11:15:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 04:40:34

US3762177

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	21 Sep 2020 13:58:22

US3762177

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered '10 Sep 2020'	James Lovette (b) (4) (b) (4)	21 Sep 2020 13:58:22

US3762177

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	James Lovette (b) (4) (b) (4)	21 Sep 2020 13:58:22

US3762177

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	James Lovette (b) (4) (b) (4)	21 Sep 2020 13:58:22

US3762177

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	21 Sep 2020 13:58:28

US3762177

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:26

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 13:58:28

US3762177

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User closed query 'Per SARS-CoV-2 Lab Recon: it appears GCL has an Illness sample dated 18SEP2020 which has not been received by GCL; however there is no record in EDC. Please reconcile and make all appropriate updates or clarify. If shipped already, please provide air bill tracker number' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 09:16:29
Query 'Per SARS-CoV-2 Lab Recon: it appears GCL has an Illness sample dated 18SEP2020 which has not been received by GCL; however there is no record in EDC. Please reconcile and make all appropriate updates or clarify. If shipped already, please provide air bill tracker number' answered with 'ADDED' (Site from DM).	Samantha Wheeler (b) (4)	13 Oct 2020 15:38:05
User opened query 'Per SARS-CoV-2 Lab Recon: it appears GCL has an Illness sample dated 18SEP2020 which has not been received by GCL; however there is no record in EDC. Please reconcile and make all appropriate updates or clarify. If shipped already, please provide air bill tracker number' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 12:09:39
User entered 'Yes (Y)'	James Lovette (b) (4)	21 Sep 2020 14:04:38

US3762177

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered '17 Sep 2020'	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:04:38

US3762177

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:04:38

US3762177

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:04:38

US3762177

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:04:44

US3762177

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:26

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 14:04:44

US3762177

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	08 Oct 2020 13:19:58

US3762177

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:26

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 1OCT2020 is reported under Visit 2 Day 29visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 22:42:33
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 1OCT2020 is reported under Visit 2 Day 29visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'date correct' (Site from DM).	Samantha Wheeler (b) (4)	24 Oct 2020 23:16:12
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 1OCT2020 is reported under Visit 2 Day 29visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 16:12:25
User entered '24 Sep 2020'	Kaitlyn Van Leuvan (b) (4)	08 Oct 2020 13:19:58

US3762177

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Kaitlyn Van Leuvan (b) (4)	08 Oct 2020 13:19:58

US3762177

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Kaitlyn Van Leuvan (b) (4)	08 Oct 2020 13:19:58

US3762177

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	08 Oct 2020 13:20:03

US3762177

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:26

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Oct 2020 13:20:03

US3762177

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:23:22

US3762177

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered '01 Oct 2020'	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:23:22

US3762177

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:23:22

US3762177

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:26

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	22 Oct 2020 21:23:22

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:26

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:24:56

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:24:56

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '01 Oct 2020'	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:24:56

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:26

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '13:34'	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:24:56

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered '01 Oct 2020 13:34'	System	22 Oct 2020 21:24:56

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:26

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.8' F	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:24:56

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:26

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:24:56

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:26

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:24:56

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '75'	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:24:56

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:26

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	22 Oct 2020 21:24:56

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered '16'	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:24:56

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	22 Oct 2020 21:24:56

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered '119'	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:24:56

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	22 Oct 2020 21:24:56

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered '77'	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:24:56

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	22 Oct 2020 21:24:56

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:26

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:24:56

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:24:56

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:24:56

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:26

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:24:56

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 21:24:56

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:26

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty.	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:24:56

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:26

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:24:56

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:26

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:24:56

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:24:56

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:26

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 21:24:56

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered empty.	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:24:56

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 21:24:56

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered empty.	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:24:56

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 21:24:56

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered empty.	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:24:56

US3762177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 21:24:56

US3762177

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:25:13

US3762177

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '01 Oct 2020'	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:25:13

US3762177

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:26

[Was study treatment given?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:34:27
User entered 'No (N)'	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:26:15

US3762177

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:26

If No, reason not given

Audit	User	Time (GMT)
User opened query 'Per CDM RQ: Please complete the dose discontinuation form located in End of Study folder. Thank you. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 22:49:16
User closed query 'Per CDM: It should only be one (1) record as the event that lead to IP withdrawal similar to fatal. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 22:49:16
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:34:27
Query 'Per CDM: It should only be one (1) record as the event that lead to IP withdrawal similar to fatal. Please review and reconcile.' answered with 'please clarify query? Should we remove exposure page? Patient did not receive second injection due to reactions from the first injection- this was PI decision. Please clarify how we should handle.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 13:47:47
User opened query 'Per CDM: It should only be one (1) record as the event that lead to IP withdrawal similar to fatal. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 10:52:58
User closed query 'Per CDM: Reason noted. However, No AE that caused the Investigational Product to be withdrawn is recorded in the AE CRF. Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 10:52:58
Query 'Per CDM: Reason noted. However, No AE that caused the Investigational Product to be withdrawn is recorded in the AE CRF. Please review and reconcile. ' answered with 'subject had many AE's that caused discontinuation of IP. Should we put this on every AE from first injection?' (Site from DM).	Samantha Wheeler (b) (4)	10 Nov 2020 19:08:52
User opened query 'Per CDM: Reason noted. However, No AE that caused the Investigational Product to be withdrawn is recorded in the AE CRF. Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 07:14:57
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)'	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:26:15

US3762177

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:34:27
User entered 'Severe reaction after first vaccination.'	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:26:15

US3762177

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:26

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 21:26:15

US3762177

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:26

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:34:27
User entered empty.	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:26:15

US3762177

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:26

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:34:27
User entered empty.	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:26:15

US3762177

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:26

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 21:26:15

US3762177

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:26

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:34:27
User entered empty.	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:26:15

US3762177

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:26

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:34:27
User entered empty.	System	22 Oct 2020 21:26:15

US3762177

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:26

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 21:26:15

US3762177

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:26:38

US3762177

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered '01 Oct 2020'	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:26:38

US3762177

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:26

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '14:00'	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:26:38

US3762177

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:26

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 14:00'	System	22 Oct 2020 21:26:38

US3762177

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered '01 Oct 2020'	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:26:54

US3762177

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:15:26

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:26:54

US3762177

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:15:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:26:54

US3762177

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:15:26

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered '14:01'	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:26:54

US3762177

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:15:26

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 14:01'	System	22 Oct 2020 21:26:54

US3762177

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:15:26

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:26:54

US3762177

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:15:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:26:54

US3762177

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:15:26

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:26:54

US3762177

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:15:26

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 21:26:54

US3762177

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:27:01

US3762177

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:26

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 21:27:01

US3762177

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:27:20

US3762177

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered '08 Oct 2020'	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:27:20

US3762177

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:27:20

US3762177

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:27:20

US3762177

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:27:25

US3762177

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:26

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 21:27:25

US3762177

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:27:42

US3762177

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered '15 Oct 2020'	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:27:42

US3762177

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:27:42

US3762177

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:27:42

US3762177

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:27:47

US3762177

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:26

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 21:27:47

US3762177

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:28:05

US3762177

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered '22 Oct 2020'	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:28:05

US3762177

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:28:05

US3762177

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:28:05

US3762177

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	22 Oct 2020 21:28:10

US3762177

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:26

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 21:28:10

US3762177

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 14:04:10

US3762177

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered '05 Nov 2020'	Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 14:04:10

US3762177

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 14:04:10

US3762177

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:26

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	09 Nov 2020 14:04:10

US3762177

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 14:04:46

US3762177

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '05 Nov 2020'	Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 14:04:46

US3762177

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:26

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '12:32'	Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 14:04:46

US3762177

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered '05 Nov 2020 12:32'	System	09 Nov 2020 14:04:46

US3762177

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:26

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.0' F	Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 14:04:46

US3762177

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:26

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 14:04:46

US3762177

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:26

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 14:04:46

US3762177

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '72'	Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 14:04:46

US3762177

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:26

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	09 Nov 2020 14:04:46

US3762177

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered '17'	Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 14:04:46

US3762177

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	09 Nov 2020 14:04:46

US3762177

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered '122'	Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 14:04:46

US3762177

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Nov 2020 14:04:46

US3762177

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered '74'	Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 14:04:46

US3762177

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Nov 2020 14:04:46

US3762177

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 14:04:53

US3762177

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 14:04:53

US3762177

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 14:05:07

US3762177

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered '05 Nov 2020'	Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 14:05:07

US3762177

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:26

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '12:36'	Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 14:05:07

US3762177

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:26

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '05 Nov 2020 12:36'	System	09 Nov 2020 14:05:07

US3762177

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 14:05:12

US3762177

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:26

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Nov 2020 14:05:12

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 18:08:00
User entered 'Day 64'	System	03 Sep 2020 18:08:00

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-03T00:04:58', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'cbd2a3bd-35ae-4d2d-b122-b15b092e8fae' User entered 'No (N)'	System	03 Nov 2020 05:05:12
	System	03 Nov 2020 05:05:12

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

Have you been exposed to someone with 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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-03T00:05:03', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'cbd2a3bd-35ae-4d2d-b122-b15b092e8fae' User entered 'No (N)'	System	03 Nov 2020 05:05:12

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-03T00:05:08', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'cbd2a3bd-35ae-4d2d-b122-b15b092e8fae' User entered '03 Nov 2020 00:05:08'	System	03 Nov 2020 05:05:12
	System	03 Nov 2020 05:05:12

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 18:08:00
User entered '03 Nov 2020 00:01'	System	03 Sep 2020 18:08:00

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 18:08:00
User entered '07 Nov 2020 23:59'	System	03 Sep 2020 18:08:00

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 18:08:00
User entered 'Day 71'	System	03 Sep 2020 18:08:00

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-12T08:32:36', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '6e7b3574-d7e7-4d75-ad86-719bb0c05410'	System	12 Nov 2020 13:32:47
User entered 'No (N)'	System	12 Nov 2020 13:32:47

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

Have you been exposed to someone with 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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-12T08:32:39', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '6e7b3574-d7e7-4d75-ad86-719bb0c05410'	System	12 Nov 2020 13:32:47
User entered 'No (N)'	System	12 Nov 2020 13:32:47

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-12T08:32:43', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: '6e7b3574-d7e7-4d75-ad86-719bb0c05410' User entered '12 Nov 2020 08:32:43'	System	12 Nov 2020 13:32:47
	System	12 Nov 2020 13:32:47

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 18:08:00
User entered '10 Nov 2020 00:01'	System	03 Sep 2020 18:08:00

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 18:08:00
User entered '14 Nov 2020 23:59'	System	03 Sep 2020 18:08:00

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 18:08:00
User entered 'Day 78'	System	03 Sep 2020 18:08:00

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-17T11:45:43', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fb818187-0f96-47d3-a3ad-3f0a2d880581'	System	17 Nov 2020 16:46:53
User entered 'Yes (Y)'	System	17 Nov 2020 16:46:53

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

Have you been exposed to someone with 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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-17T11:45:55', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fb818187-0f96-47d3-a3ad-3f0a2d880581'	System	17 Nov 2020 16:46:53
User entered 'No (N)'	System	17 Nov 2020 16:46:53

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-17T11:46:02', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fb818187-0f96-47d3-a3ad-3f0a2d880581'	System	17 Nov 2020 16:46:53
User entered 'Yes (Y)'	System	17 Nov 2020 16:46:53

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-17T11:46:23', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fb818187-0f96-47d3-a3ad-3f0a2d880581' User entered '0'	System	17 Nov 2020 16:46:53
	System	17 Nov 2020 16:46:53

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-17T11:46:23', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fb818187-0f96-47d3-a3ad-3f0a2d880581' User entered '0'	System	17 Nov 2020 16:46:53
	System	17 Nov 2020 16:46:53

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-17T11:46:23', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fb818187-0f96-47d3-a3ad-3f0a2d880581' User entered '0'	System	17 Nov 2020 16:46:53
	System	17 Nov 2020 16:46:53

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-17T11:46:23', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fb818187-0f96-47d3-a3ad-3f0a2d880581' User entered '0'	System	17 Nov 2020 16:46:53
	System	17 Nov 2020 16:46:53

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-17T11:46:23', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fb818187-0f96-47d3-a3ad-3f0a2d880581' User entered '0'	System	17 Nov 2020 16:46:53
	System	17 Nov 2020 16:46:53

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-17T11:46:23', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fb818187-0f96-47d3-a3ad-3f0a2d880581'	System	17 Nov 2020 16:46:53
User entered '1'	System	17 Nov 2020 16:46:53

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-17T11:46:23', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fb818187-0f96-47d3-a3ad-3f0a2d880581' User entered '0'	System	17 Nov 2020 16:46:53
	System	17 Nov 2020 16:46:53

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-17T11:46:23', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fb818187-0f96-47d3-a3ad-3f0a2d880581' User entered '1'	System	17 Nov 2020 16:46:53
	System	17 Nov 2020 16:46:53

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-17T11:46:23', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fb818187-0f96-47d3-a3ad-3f0a2d880581' User entered '0'	System	17 Nov 2020 16:46:53
	System	17 Nov 2020 16:46:53

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-17T11:46:23', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fb818187-0f96-47d3-a3ad-3f0a2d880581'	System	17 Nov 2020 16:46:53
User entered '0'	System	17 Nov 2020 16:46:53

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-17T11:46:23', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fb818187-0f96-47d3-a3ad-3f0a2d880581' User entered '0'	System	17 Nov 2020 16:46:53
	System	17 Nov 2020 16:46:53

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-17T11:46:23', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fb818187-0f96-47d3-a3ad-3f0a2d880581'	System	17 Nov 2020 16:46:53
User entered '0'	System	17 Nov 2020 16:46:53

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-17T11:46:23', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fb818187-0f96-47d3-a3ad-3f0a2d880581' User entered '1'	System	17 Nov 2020 16:46:53
	System	17 Nov 2020 16:46:53

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-17T11:46:23', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fb818187-0f96-47d3-a3ad-3f0a2d880581'	System	17 Nov 2020 16:46:53
User entered '1'	System	17 Nov 2020 16:46:53

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-17T11:46:23', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fb818187-0f96-47d3-a3ad-3f0a2d880581' User entered '0'	System	17 Nov 2020 16:46:53
	System	17 Nov 2020 16:46:53

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-17T11:46:23', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fb818187-0f96-47d3-a3ad-3f0a2d880581'	System	17 Nov 2020 16:46:53
User entered '1'	System	17 Nov 2020 16:46:53

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-17T11:46:23', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fb818187-0f96-47d3-a3ad-3f0a2d880581'	System	17 Nov 2020 16:46:53
User entered '1'	System	17 Nov 2020 16:46:53

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-17T11:46:32', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fb818187-0f96-47d3-a3ad-3f0a2d880581'	System	17 Nov 2020 16:46:53
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	17 Nov 2020 16:46:53

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-17T11:46:40', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fb818187-0f96-47d3-a3ad-3f0a2d880581'	System	17 Nov 2020 16:46:53
User entered 'No (N)'	System	17 Nov 2020 16:46:53

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-17T11:46:43', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'fb818187-0f96-47d3-a3ad-3f0a2d880581' User entered '17 Nov 2020 11:46:43'	System	17 Nov 2020 16:46:53
	System	17 Nov 2020 16:46:53

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 18:08:00
User entered '17 Nov 2020 00:01'	System	03 Sep 2020 18:08:00

US3762177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 18:08:00
User entered '21 Nov 2020 23:59'	System	03 Sep 2020 18:08:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '31 Oct 2020 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '04 Nov 2020 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '07 Nov 2020 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '11 Nov 2020 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '14 Nov 2020 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '18 Nov 2020 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-23T12:19:50', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'ec9b15b4-07a6-4f4b-afac-3a31242e1ac9'	System	23 Nov 2020 17:19:59
User entered 'No (N)'	System	23 Nov 2020 17:19:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

Have you been exposed to someone with 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 (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-23T12:19:46', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'ec9b15b4-07a6-4f4b-afac-3a31242e1ac9'	System	23 Nov 2020 17:19:59
User entered 'No (N)'	System	23 Nov 2020 17:19:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3881E7F-D8A0-48F6-902D-D669CBC7F8ED)', Time: '2020-11-23T12:19:54', User OID: 'PatientReportedOutcome (US3762177)', ODM File OID: 'ec9b15b4-07a6-4f4b-afac-3a31242e1ac9' User entered '23 Nov 2020 12:19:54'	System	23 Nov 2020 17:19:59
	System	23 Nov 2020 17:19:59

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 03:26:00

US3762177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:26:00
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 03:26:00

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:15:26

[Date of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:26:13
User entered '18 Sep 2020'	Samantha Wheeler (b) (4)	13 Oct 2020 15:31:15
	(b) (4)	

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:15:26

[Time of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:26:13
User entered '10:00'	Samantha Wheeler (b) (4)	13 Oct 2020 15:31:15
	(b) (4)	

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:15:26

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 10:00'	System	13 Oct 2020 15:31:15

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:15:26

[Type of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:26:13
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:31:15

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[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:26:13
User entered 'Yes (Y)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:31:15
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:26

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 1 (Day 1)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:33:11
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

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[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered '19 Sep 2020'	Samantha Wheeler (b) (4)	13 Oct 2020 15:33:11
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:26

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered '0'	Samantha Wheeler (b) (4)	13 Oct 2020 15:33:11
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:26

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered '100'	Samantha Wheeler (b) (4)	13 Oct 2020 15:33:11
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:26

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	13 Oct 2020 15:33:11

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:26

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered '97.7' F	Samantha Wheeler (b) (4)	13 Oct 2020 15:33:11
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:26

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:33:11
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:26

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:33:11
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:26

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:33:11
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:26

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:33:11
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:26

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'Moderate (Moderate)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:33:11
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:26

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:33:11
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:26

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'Moderate (Moderate)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:33:11
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:26

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:33:11
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:26

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:33:11
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:26

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:33:11
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:26

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:33:11
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:26

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:33:11
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:26

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:33:11
	(b) (4)	

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Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:26

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:33:11
	(b) (4)	

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Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:26

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:33:11
	(b) (4)	

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Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:26

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:33:11
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:26

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 2 (Day 2)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:34:20
	(b) (4)	

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Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:26

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered '20 Sep 2020'	Samantha Wheeler (b) (4)	13 Oct 2020 15:34:20
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:26

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered '0'	Samantha Wheeler (b) (4)	13 Oct 2020 15:34:20
	(b) (4)	

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Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:26

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered '100'	Samantha Wheeler (b) (4)	13 Oct 2020 15:34:20
	(b) (4)	

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Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:26

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	13 Oct 2020 15:34:20

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Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:26

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered '96.5' F	Samantha Wheeler (b) (4)	13 Oct 2020 15:34:20
	(b) (4)	

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Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:26

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:34:20
	(b) (4)	

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Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:26

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:34:20
	(b) (4)	

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Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:26

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:34:20
	(b) (4)	

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Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:26

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:34:20
	(b) (4)	

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Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:26

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'Mild (Mild)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:34:20
	(b) (4)	

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Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:26

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:34:20
	(b) (4)	

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Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:26

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'Mild (Mild)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:34:20
	(b) (4)	

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Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:26

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:34:20
	(b) (4)	

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Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:26

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:34:20
	(b) (4)	

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Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:26

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:34:20
	(b) (4)	

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Form: Symptom Log (2)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:34:20
	(b) (4)	

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Form: Symptom Log (2)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:34:20
	(b) (4)	

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Form: Symptom Log (2)

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:34:20
	(b) (4)	

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Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:26

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:34:20
	(b) (4)	

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Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:26

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:34:20
	(b) (4)	

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Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:26

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:34:20
	(b) (4)	

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Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:26

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 3 (Day 3)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:35:12
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:26

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered '21 Sep 2020'	Samantha Wheeler (b) (4)	13 Oct 2020 15:35:12
	(b) (4)	

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Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:26

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered '0'	Samantha Wheeler (b) (4)	13 Oct 2020 15:35:12
	(b) (4)	

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Form: Symptom Log (3)

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[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered missing code ND - Not Done.	Samantha Wheeler (b) (4)	13 Oct 2020 15:35:12
	(b) (4)	

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Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:26

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	13 Oct 2020 15:35:12

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Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:26

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered missing code ND - Not Done.	Samantha Wheeler (b) (4)	13 Oct 2020 15:35:12
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:26

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:35:12
	(b) (4)	

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Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:26

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:35:12
	(b) (4)	

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Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:26

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:35:12
	(b) (4)	

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Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:26

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:35:12
	(b) (4)	

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Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:26

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:35:12
	(b) (4)	

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Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:26

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:35:12
	(b) (4)	

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Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:26

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:35:12
	(b) (4)	

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Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:26

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:35:12
	(b) (4)	

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Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:26

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:35:12
	(b) (4)	

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Form: Symptom Log (3)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:35:12
	(b) (4)	

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Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:26

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:35:12
	(b) (4)	

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Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:26

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:35:12
	(b) (4)	

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Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:26

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:35:12
	(b) (4)	

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Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:26

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:35:12
	(b) (4)	

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:26

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:35:12
	(b) (4)	

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:26

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:34:44
User entered 'None (None)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:35:12
	(b) (4)	

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:15:26

[Date of Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Recon: GCL has SARS-CoV-2 sample with date of 18SEP2020; however Illness Visit is not completed. Please reconcile or clarify. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 22:51:33
Query 'Per GCL Lab Recon: GCL has SARS-CoV-2 sample with date of 18SEP2020; however Illness Visit is not completed. Please reconcile or clarify. ' answered with 'unscheduled visit ' (Site from DM).	Kaitlyn Van Leuvan (b) (4)	09 Nov 2020 15:35:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:27:16
User opened query 'Per GCL Lab Recon: GCL has SARS-CoV-2 sample with date of 18SEP2020; however Illness Visit is not completed. Please reconcile or clarify. ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 11:03:04
User entered '18 Sep 2020'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:36:34

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:15:26

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:27:16
User entered 'Yes (Y)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:36:34
	(b) (4)	

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:15:26

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:27:16
User entered 'No (N)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:36:34
	(b) (4)	

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:15:26

[Date of Test](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:27:16
User entered '18 Sep 2020'	Samantha Wheeler (b) (4)	13 Oct 2020 15:36:34
	(b) (4)	

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:15:26

[Type of Test Performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:27:16
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:36:34

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:15:26

[Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:27:16
User entered empty.	Samantha Wheeler (b) (4)	13 Oct 2020 15:36:34
	(b) (4)	

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:15:26

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:27:16
User entered 'No (N)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:36:34
	(b) (4)	

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:15:26

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:27:16
User entered empty.	Samantha Wheeler (b) (4)	13 Oct 2020 15:36:34
	(b) (4)	

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:15:26

[CLIA Certified?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:27:16
User entered empty.	Samantha Wheeler (b) (4)	13 Oct 2020 15:36:34
	(b) (4)	

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:15:26

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	13 Oct 2020 15:36:34

US3762177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 11:15:26

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:37:03

US3762177

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 11:15:26

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 20:06:27

US3762177

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 11:15:26

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Samantha Wheeler (b) (4)	19 Nov 2020 20:06:27
	(b) (4)	

US3762177

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 11:15:26

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020'	Samantha Wheeler (b) (4)	19 Nov 2020 20:06:27
	(b) (4)	

US3762177

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 11:15:26

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Samantha Wheeler (b) (4)	19 Nov 2020 20:06:27
	(b) (4)	

US3762177

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 11:15:26

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Samantha Wheeler (b) (4)	19 Nov 2020 20:06:27
	(b) (4)	

US3762177

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 11:15:26

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Samantha Wheeler (b) (4)	19 Nov 2020 20:06:27
	(b) (4)	

US3762177

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 11:15:26

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Samantha Wheeler (b) (4)	19 Nov 2020 20:06:27
	(b) (4)	

US3762177

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 11:15:26

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 20:06:27

US3762177

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 11:15:26

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Samantha Wheeler (b) (4)	19 Nov 2020 20:06:27
	(b) (4)	

US3762177

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 11:15:26

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Samantha Wheeler (b) (4)	19 Nov 2020 20:06:27
	(b) (4)	

US3762177

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 11:15:26

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Samantha Wheeler (b) (4)	19 Nov 2020 20:06:27
	(b) (4)	

US3762177

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 11:15:26

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Samantha Wheeler (b) (4)	19 Nov 2020 20:06:27
	(b) (4)	

US3762177

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 11:15:26

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 20:06:27

US3762177

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 11:15:26

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Samantha Wheeler (b) (4)	19 Nov 2020 20:06:27
	(b) (4)	

US3762177

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 11:15:26

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Samantha Wheeler (b) (4)	19 Nov 2020 20:06:27
	(b) (4)	

US3762177

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 11:15:26

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 20:06:27

US3762177

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 11:15:26

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Samantha Wheeler (b) (4)	19 Nov 2020 20:06:27
	(b) (4)	

US3762177

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 11:15:26

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 20:06:27

US3762177

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 11:15:26

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 20:06:27

US3762177

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 11:15:26

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Samantha Wheeler (b) (4)	19 Nov 2020 20:06:27
	(b) (4)	

US3762177

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 11:15:26

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Samantha Wheeler (b) (4)	19 Nov 2020 20:06:27
	(b) (4)	

US3762177

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 20:02:40

US3762177

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered '18 Sep 2020'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 20:02:40

US3762177

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 20:02:40

US3762177

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:26

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	19 Nov 2020 20:02:40

US3762177

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 20:03:28

US3762177

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '18 Sep 2020'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 20:03:28

US3762177

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:26

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '10:00'	Samantha Wheeler (b) (4)	19 Nov 2020 20:03:28
	(b) (4)	

US3762177

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered '18 Sep 2020 10:00'	System	19 Nov 2020 20:03:28

US3762177

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User closed query 'Height reported is out of range <= 121.92cm (48in) OR >= 228.6cm (90in). Please reconcile.' (Site from System).	System	19 Nov 2020 20:03:46
Query 'Height reported is out of range <= 121.92cm (48in) OR >= 228.6cm (90in). Please reconcile.' answered by data change (Site from System).	System	19 Nov 2020 20:03:46
User entered '63' in reason for change: Data Entry Error	Samantha Wheeler (b) (4)	19 Nov 2020 20:03:46
User opened query 'Height reported is out of range <= 121.92cm (48in) OR >= 228.6cm (90in). Please reconcile.' (Site from System).	System	19 Nov 2020 20:03:28
User entered '145' in	Samantha Wheeler (b) (4)	19 Nov 2020 20:03:28
DataPoint set to visible.	System	19 Nov 2020 20:02:40

US3762177

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User closed query 'Weight reported is out of range <= 30kg (66lbs) or >= 181.818kg (400lbs). Please reconcile.' (Site from System).	System	19 Nov 2020 20:03:46
Query 'Weight reported is out of range <= 30kg (66lbs) or >= 181.818kg (400lbs). Please reconcile.' answered by data change (Site from System).	System	19 Nov 2020 20:03:46
User entered '145' lb reason for change: Data Entry Error	Samantha Wheeler (b) (4)	19 Nov 2020 20:03:46
User opened query 'Weight reported is out of range <= 30kg (66lbs) or >= 181.818kg (400lbs). Please reconcile.' (Site from System).	System	19 Nov 2020 20:03:28
User entered '63' lb	Samantha Wheeler (b) (4)	19 Nov 2020 20:03:28
DataPoint set to visible.	System	19 Nov 2020 20:02:40

US3762177

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:26

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.8' F	Samantha Wheeler (b) (4)	19 Nov 2020 20:03:28
	(b) (4)	

US3762177

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:26

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Samantha Wheeler (b) (4)	19 Nov 2020 20:03:28
	(b) (4)	

US3762177

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:26

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Samantha Wheeler (b) (4)	19 Nov 2020 20:03:28
	(b) (4)	

US3762177

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '70'	Samantha Wheeler (b) (4)	19 Nov 2020 20:03:28
	(b) (4)	

US3762177

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:26

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	19 Nov 2020 20:03:28

US3762177

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered '16'	Samantha Wheeler (b) (4)	19 Nov 2020 20:03:28
	(b) (4)	

US3762177

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	19 Nov 2020 20:03:28

US3762177

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered '125'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 20:03:28

US3762177

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Nov 2020 20:03:28

US3762177

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
User entered '68'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 20:03:28

US3762177

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Nov 2020 20:03:28

US3762177

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Samantha Wheeler (b) (4)	19 Nov 2020 20:04:02
	(b) (4)	

US3762177

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '18 Sep 2020'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 20:04:02

US3762177

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 11:15:26

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Samantha Wheeler (b) (4)	19 Nov 2020 20:04:18
	(b) (4)	

US3762177

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 11:15:26

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020'	Samantha Wheeler (b) (4)	19 Nov 2020 20:04:18
	(b) (4)	

US3762177

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:15:26

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: refer to log line 1, 2, 3, and 4. Action taken is recorded as IP withdrawal for log line 1,2,3 and 4. This action taken should only be selected for 1 event-the primary reason for discontinuation of IP. Please update. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 22:47:34
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:28:52
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:09:16

US3762177

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:26

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:32:00
User closed query 'Per DM CLR: Please review and reflect the specific Type (e.g., Macular, Papular, etc) of REDNESS and if this is Urticarial or Non-Urticarial. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 16:27:31
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site erythema, LLT: Injection site redness - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 06:30:46
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 06:30:46
Data point term sent to Coder	System	10 Nov 2020 18:59:37
Query 'Per DM CLR: Please review and reflect the specific Type (e.g., Macular, Papular, etc) of REDNESS and if this is Urticarial or Non-Urticarial. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' answered with 'updated' (Site from DM).	Samantha Wheeler (b) (4) (b) (4)	10 Nov 2020 18:59:35
DataPoint Un-verified.	Samantha Wheeler (b) (4) (b) (4)	10 Nov 2020 18:59:29
Coding entries removed.	Samantha Wheeler (b) (4) (b) (4)	10 Nov 2020 18:59:29
User entered 'INJECTION SITE REDNESS, LEFT ARM non-urticarial' reason for change: Data Entry Error	Samantha Wheeler (b) (4) (b) (4)	10 Nov 2020 18:59:29
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User opened query 'Per DM CLR: Please review and reflect the specific Type (e.g., Macular, Papular, etc) of REDNESS and if this is Urticarial or Non-Urticarial. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 06:13:02

US3762177

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:26

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site erythema, LLT: Injection site redness - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 14:13:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 14:13:40
Data point term sent to Coder	System	21 Sep 2020 14:12:27
User entered 'INJECTION SITE REDNESS, LEFT ARM'	James Lovette (b) (4)	21 Sep 2020 14:11:48

US3762177

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'No (N)'	James Lovette (b) (4)	21 Sep 2020 14:11:48
	(b) (4)	

US3762177

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:11:48

US3762177

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:26

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'No (N)'	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:11:48

US3762177

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '03 Sep 2020'	James Lovette (b) (4)	21 Sep 2020 14:11:48
	(b) (4)	

US3762177

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:26

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '00:00'	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:11:48

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:26

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 00:00'	System	21 Sep 2020 14:11:48

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:26

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'Yes (Y)'	James Lovette (b) (4)	21 Sep 2020 14:11:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:26

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4)	21 Sep 2020 14:11:48
	(b) (4)	

US3762177

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:26

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4)	21 Sep 2020 14:11:48
	(b) (4)	

US3762177

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 14:11:48

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:26

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:11:48

US3762177

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'No (N)'	James Lovette (b) (4)	21 Sep 2020 14:11:48
	(b) (4)	

US3762177

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:26

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	James Lovette (b) (4)	21 Sep 2020 14:11:48
	(b) (4)	

US3762177

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:26

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	James Lovette (b) (4)	21 Sep 2020 14:11:48
	(b) (4)	

US3762177

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:11:48

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:26

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4)	21 Sep 2020 14:11:48
	(b) (4)	

US3762177

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:26

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4)	21 Sep 2020 14:11:48
	(b) (4)	

US3762177

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:26

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4)	21 Sep 2020 14:11:48
	(b) (4)	

US3762177

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:26

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:11:48

US3762177

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:11:48

US3762177

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	James Lovette (b) (4)	21 Sep 2020 14:11:48
	(b) (4)	

US3762177

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:26

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:11:48

US3762177

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Per CCGs p. 34, Relationship to investigational product and Relationship to Study Procedure should be "Not Applicable" if clinical event is prior to first dose of investigational product. Kindly review and reconcile as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 10:21:43
Query 'Per CDM: Per CCGs p. 34, Relationship to investigational product and Relationship to Study Procedure should be "Not Applicable" if clinical event is prior to first dose of investigational product. Kindly review and reconcile as appropriate. ' answered with 'this began after first dose of IP' (Site from DM).	Samantha Wheeler (b) (4)	10 Nov 2020 19:00:12
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User opened query 'Per CDM: Per CCGs p. 34, Relationship to investigational product and Relationship to Study Procedure should be "Not Applicable" if clinical event is prior to first dose of investigational product. Kindly review and reconcile as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 13:53:44
User entered 'Related (RELATED)'	James Lovette (b) (4)	21 Sep 2020 14:11:48

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'Related (RELATED)'	James Lovette (b) (4)	21 Sep 2020 14:11:48
	(b) (4)	

US3762177

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:26

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:26:06
DataPoint Un-verified.	Samantha Wheeler (b) (4)	19 Nov 2020 15:51:41
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	19 Nov 2020 15:51:41
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'None (NONE)'	James Lovette (b) (4)	21 Sep 2020 14:11:48

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:26

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '1'	James Lovette (b) (4)	21 Sep 2020 14:11:48
	(b) (4)	

US3762177

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:11:48

US3762177

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	James Lovette (b) (4)	21 Sep 2020 14:11:48
	(b) (4)	

US3762177

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:26

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:11:48

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:26

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:11:48

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:26

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:11:48

US3762177

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:26

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	21 Sep 2020 14:11:48

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:26

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	21 Sep 2020 14:11:48

US3762177

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:26

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per MM, Please confirm if subject received second dose of IP' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 23:34:56
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 23:34:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection' answered with 'patient did come in for illness visit' (Site from DM).	Samantha Wheeler (b) (4)	24 Oct 2020 23:39:51
Query 'Per MM, Please confirm if subject received second dose of IP' answered with 'subject did not receive second dose of IP' (Site from DM).	Samantha Wheeler (b) (4)	24 Oct 2020 23:39:41
User opened query 'Per MM, Please confirm if subject received second dose of IP' (Site from DM).	(b) (4), (b) (6)	17 Oct 2020 14:51:19
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection' (Site from DM).	(b) (4), (b) (6)	17 Oct 2020 14:50:54
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\23.0.	Coder Import (b) (4)	21 Sep 2020 14:15:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	21 Sep 2020 14:15:51
Data point term sent to Coder	System	21 Sep 2020 14:14:32
User entered 'FATIGUE'	James Lovette (b) (4)	21 Sep 2020 14:14:01

US3762177

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'No (N)'	James Lovette (b) (4)	21 Sep 2020 14:14:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:14:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:26

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'No (N)'	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:14:01

US3762177

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '04 Sep 2020'	James Lovette (b) (4)	21 Sep 2020 14:14:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:26

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '00:00'	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:14:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:26

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 00:00'	System	21 Sep 2020 14:14:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:26

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'Yes (Y)'	James Lovette (b) (4)	21 Sep 2020 14:14:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:26

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4)	21 Sep 2020 14:14:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:26

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4)	21 Sep 2020 14:14:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 14:14:01

US3762177

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:26

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:14:01

US3762177

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'No (N)'	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:14:01

US3762177

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:26

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	James Lovette (b) (4)	21 Sep 2020 14:14:01
	(b) (4)	

US3762177

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:26

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	James Lovette (b) (4)	21 Sep 2020 14:14:01
	(b) (4)	

US3762177

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:14:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:26

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4)	21 Sep 2020 14:14:01
	(b) (4)	

US3762177

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:26

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4)	21 Sep 2020 14:14:01
	(b) (4)	

US3762177

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:26

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4)	21 Sep 2020 14:14:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:26

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:14:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:14:01

US3762177

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	James Lovette (b) (4)	21 Sep 2020 14:14:01
	(b) (4)	

US3762177

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:26

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	James Lovette (b) (4)	21 Sep 2020 14:14:01
	(b) (4)	

US3762177

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'Related (RELATED)'	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:14:01

US3762177

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'Related (RELATED)'	James Lovette (b) (4)	21 Sep 2020 14:14:01
	(b) (4)	

US3762177

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:26

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:26:29
DataPoint Un-verified.	Samantha Wheeler (b) (4)	19 Nov 2020 15:51:52
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	19 Nov 2020 15:51:52
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'None (NONE)'	James Lovette (b) (4)	21 Sep 2020 14:14:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:26

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '1'	James Lovette (b) (4)	21 Sep 2020 14:14:01
	(b) (4)	

US3762177

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	James Lovette (b) (4)	21 Sep 2020 14:14:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	James Lovette (b) (4)	21 Sep 2020 14:14:01
	(b) (4)	

US3762177

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:26

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:14:01

US3762177

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:26

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:14:01

US3762177

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:26

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4)	21 Sep 2020 14:14:01
	(b) (4)	

US3762177

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:26

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	21 Sep 2020 14:14:01

US3762177

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:26

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	21 Sep 2020 14:14:01

US3762177

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:26

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Gastrointestinal and abdominal pains (excl oral and throat), PT: Abdominal pain upper, LLT: Stomach ache - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 14:16:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 14:16:43
Data point term sent to Coder	System	21 Sep 2020 14:15:34
User entered 'STOMACH ACHE'	James Lovette (b) (4)	21 Sep 2020 14:15:22
	(b) (4)	

US3762177

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'No (N)'	James Lovette (b) (4)	21 Sep 2020 14:15:22
	(b) (4)	

US3762177

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User closed query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, stomach ache is not a solicited event for this study. Please review and update response to 'Was this a Solicited Adverse Reaction?' as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 14:13:13
Query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, stomach ache is not a solicited event for this study. Please review and update response to 'Was this a Solicited Adverse Reaction?' as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	Samantha Wheeler (b) (4) (b) (4)	24 Oct 2020 23:40:13
User entered 'No (N)' reason for change: Data Entry Error	Samantha Wheeler (b) (4) (b) (4)	24 Oct 2020 23:40:06
User opened query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, stomach ache is not a solicited event for this study. Please review and update response to 'Was this a Solicited Adverse Reaction?' as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 20:47:50
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:15:22

US3762177

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:26

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'No (N)'	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:15:22

US3762177

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '13 Sep 2020'	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:15:22

US3762177

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:26

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4)	21 Sep 2020 14:15:22
	(b) (4)	

US3762177

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:26

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 14:15:22

US3762177

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:26

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'Yes (Y)'	James Lovette (b) (4)	21 Sep 2020 14:15:22
	(b) (4)	

US3762177

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:26

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4)	21 Sep 2020 14:15:22
	(b) (4)	

US3762177

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:26

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4)	21 Sep 2020 14:15:22
	(b) (4)	

US3762177

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 14:15:22

US3762177

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:26

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:15:22

US3762177

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'No (N)'	James Lovette (b) (4)	21 Sep 2020 14:15:22
	(b) (4)	

US3762177

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:26

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:15:22

US3762177

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:26

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	James Lovette (b) (4)	21 Sep 2020 14:15:22
	(b) (4)	

US3762177

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:15:22

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:26

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4)	21 Sep 2020 14:15:22
	(b) (4)	

US3762177

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:26

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4)	21 Sep 2020 14:15:22
	(b) (4)	

US3762177

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:26

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:15:22

US3762177

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:26

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:15:22

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:15:22

US3762177

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	James Lovette (b) (4)	21 Sep 2020 14:15:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:26

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	James Lovette (b) (4)	21 Sep 2020 14:15:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'Related (RELATED)'	James Lovette (b) (4)	21 Sep 2020 14:15:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'Related (RELATED)'	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:15:22

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:26

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:26:54
DataPoint Un-verified.	Samantha Wheeler (b) (4)	19 Nov 2020 15:52:12
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	19 Nov 2020 15:52:12
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'None (NONE)'	James Lovette (b) (4)	21 Sep 2020 14:15:22

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:26

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '1'	James Lovette (b) (4)	21 Sep 2020 14:15:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	James Lovette (b) (4)	21 Sep 2020 14:15:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	James Lovette (b) (4)	21 Sep 2020 14:15:22
	(b) (4)	

US3762177

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:26

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:15:22

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:26

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:15:22

US3762177

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:26

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:15:22

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:26

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	21 Sep 2020 14:15:22

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:26

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	21 Sep 2020 14:15:22

US3762177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:26

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Pain, LLT: General body pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 14:18:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 14:18:39
Data point term sent to Coder	System	21 Sep 2020 14:17:35
User entered 'INTERMITTENT BODY ACHES'	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:16:35

US3762177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'No (N)'	James Lovette (b) (4)	21 Sep 2020 14:16:35
	(b) (4)	

US3762177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User closed query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, Body Aches is not a solicited event for this study. Please review and update response to 'Was this a Solicited Adverse Reaction?' as appropriate. Otherwise, update AE term to record the actual solicited event term.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 17:24:36
Query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, Body Aches is not a solicited event for this study. Please review and update response to 'Was this a Solicited Adverse Reaction?' as appropriate. Otherwise, update AE term to record the actual solicited event term.' answered with 'updated per query' (Site from DM).	Samantha Wheeler (b) (4)	24 Oct 2020 23:50:51
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	24 Oct 2020 23:50:45
User opened query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, Body Aches is not a solicited event for this study. Please review and update response to 'Was this a Solicited Adverse Reaction?' as appropriate. Otherwise, update AE term to record the actual solicited event term.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 20:47:31
User entered 'Yes (Y)'	James Lovette (b) (4)	21 Sep 2020 14:16:35

US3762177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:26

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'No (N)'	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:16:35

US3762177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '04 Sep 2020'	James Lovette (b) (4)	21 Sep 2020 14:16:35
	(b) (4)	

US3762177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:26

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 14:16:50
User entered '00:00' reason for change: Data Entry Error	James Lovette (b) (4)	21 Sep 2020 14:16:50
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 14:16:35
User entered empty.	James Lovette (b) (4)	21 Sep 2020 14:16:35

US3762177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:26

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 00:00'	System	21 Sep 2020 14:16:50
User entered empty.	System	21 Sep 2020 14:16:35

US3762177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:26

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'Yes (Y)'	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:16:35

US3762177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:26

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4)	21 Sep 2020 14:16:35
	(b) (4)	

US3762177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:26

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4)	21 Sep 2020 14:16:35
	(b) (4)	

US3762177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 14:16:35

US3762177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:26

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:16:35

US3762177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'No (N)'	James Lovette (b) (4)	21 Sep 2020 14:16:35
	(b) (4)	

US3762177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:26

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	James Lovette (b) (4)	21 Sep 2020 14:16:35
	(b) (4)	

US3762177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:26

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	James Lovette (b) (4)	21 Sep 2020 14:16:35
	(b) (4)	

US3762177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:16:35

US3762177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:26

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4)	21 Sep 2020 14:16:35
	(b) (4)	

US3762177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:26

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4)	21 Sep 2020 14:16:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:26

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4)	21 Sep 2020 14:16:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:26

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:16:35

US3762177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:16:35

US3762177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	James Lovette (b) (4)	21 Sep 2020 14:16:35
	(b) (4)	

US3762177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:26

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:16:35

US3762177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'Related (RELATED)'	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:16:35

US3762177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'Related (RELATED)'	James Lovette (b) (4)	21 Sep 2020 14:16:35
	(b) (4)	

US3762177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:26

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:27:14
DataPoint Un-verified.	Samantha Wheeler (b) (4)	19 Nov 2020 15:52:28
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	19 Nov 2020 15:52:28
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'None (NONE)'	James Lovette (b) (4)	21 Sep 2020 14:16:35

US3762177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:26

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '1'	James Lovette (b) (4)	21 Sep 2020 14:16:35
	(b) (4)	

US3762177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	James Lovette (b) (4)	21 Sep 2020 14:16:35
	(b) (4)	

US3762177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	James Lovette (b) (4)	21 Sep 2020 14:16:35
	(b) (4)	

US3762177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:26

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:16:35

US3762177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:26

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:16:35

US3762177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:26

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:16:35

US3762177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:26

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	21 Sep 2020 14:16:35

US3762177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:26

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	21 Sep 2020 14:16:35

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:26

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Vomiting, LLT: Vomiting - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 05:50:29
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 05:50:29
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
Data point term sent to Coder	System	05 Nov 2020 18:11:49
User entered 'Vomit'	(b) (4), (b) (6)	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:26

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '27 Oct 2020'	(b) (4), (b) (6)	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:26

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:26

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:26

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:26

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '27 Oct 2020'	(b) (4), (b) (6)	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:26

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:26

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:26

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:26

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:26

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:26

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:26

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:26

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:26

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:32:00
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 19:01:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Nov 2020 19:01:54
DataPoint Un-verified.	Samantha Wheeler (b) (4)	10 Nov 2020 19:01:54
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	10 Nov 2020 19:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 18:11:28
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:32:00
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 19:01:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Nov 2020 19:01:54
DataPoint Un-verified.	Samantha Wheeler (b) (4)	10 Nov 2020 19:01:54
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	10 Nov 2020 19:01:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 18:11:28
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:26

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'None (NONE)'	(b) (4), (b) (6)	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:26

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '1'	(b) (4), (b) (6)	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:26

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:26

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:26

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'Pt stated she ate leftovers on 10/26/2020 and had vomiting on 10/27/2020 and stomach pain from 10/27/2020 until Visit 3 with her PCP on 11/2/2020. PCP prescribed Ventyl PRN for stomach pains and pt took her first dose 11/3/2020. PCP indicated to the pt that this may be more related to her IBS and diverticulitis than cove study.'	(b) (4), (b) (6)	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:26

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 11:15:26

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Nov 2020 18:11:28

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:26

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Gastrointestinal and abdominal pains (excl oral and throat), PT: Abdominal pain upper, LLT: Stomach pain - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 18:13:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 18:13:21
Data point term sent to Coder	System	05 Nov 2020 18:12:52
User entered 'Stomach pains'	(b) (4), (b) (6)	05 Nov 2020 18:12:15

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 18:12:15

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 18:12:15

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:26

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 18:12:15

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '27 Oct 2020'	(b) (4), (b) (6)	05 Nov 2020 18:12:15

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:26

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 18:12:15

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:26

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 18:12:15

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:26

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 18:12:15

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:26

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 18:12:15

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:26

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 18:12:15

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 18:12:15

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:26

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	05 Nov 2020 18:12:15

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 18:12:15

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:26

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 18:12:15

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:26

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 18:12:15

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 18:12:15

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:26

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 18:12:15

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:26

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 18:12:15

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:26

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 18:12:15

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:26

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 18:12:15

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 18:12:15

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 18:12:15

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:26

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 18:12:15

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:32:00
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 19:02:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Nov 2020 19:02:26
DataPoint Un-verified.	Samantha Wheeler (b) (4)	10 Nov 2020 19:02:26
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	10 Nov 2020 19:02:26
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 18:12:15
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 18:12:15

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:32:00
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 19:02:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Nov 2020 19:02:26
DataPoint Un-verified.	Samantha Wheeler (b) (4)	10 Nov 2020 19:02:26
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	10 Nov 2020 19:02:26
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 18:12:15
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 18:12:15

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:26

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'None (NONE)'	(b) (4), (b) (6)	05 Nov 2020 18:12:15

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:26

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 18:12:15

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '1'	(b) (4), (b) (6)	05 Nov 2020 18:12:15

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 18:12:15

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:26

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	05 Nov 2020 18:12:15

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:26

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 18:12:15

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:26

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:30:25
User entered 'Pt stated she ate leftovers on 10/26/2020 and had vomiting on 10/27/2020 and stomach pain from 10/27/2020 until Visit 3 with her PCP on 11/2/2020. PCP prescribed Ventyl PRN for stomach pains and pt took her first dose 11/3/2020. PCP indicated to the pt that this may be more related to her IBS and diverticulitis than cove study.'	(b) (4), (b) (6)	05 Nov 2020 18:12:15

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:26

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	05 Nov 2020 18:12:15

US3762177

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:26

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 18:12:15

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:15:26

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 11:27:02

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:26

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
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) (b) (4)	11 Sep 2020 11:29:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 11:29:42
Data point term sent to Coder	System	11 Sep 2020 11:28:48
User entered 'Levothyroxine'	(b) (4), (b) (6)	11 Sep 2020 11:28:22

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:26

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User closed query 'Per DM CLR: Note, Prophylaxis = YES. Please verify if this field should be updated as there is a corresponding condition recorded on Medical History page. If yes, please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 19:31:59
Query 'Per DM CLR: Note, Prophylaxis = YES. Please verify if this field should be updated as there is a corresponding condition recorded on Medical History page. If yes, please update eCRF as appropriate.' answered with 'update' (Site from DM).	Samantha Wheeler (b) (4)	13 Oct 2020 15:27:22
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	13 Oct 2020 15:27:16
User opened query 'Per DM CLR: Note, Prophylaxis = YES. Please verify if this field should be updated as there is a corresponding condition recorded on Medical History page. If yes, please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 07:28:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 11:28:22

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:26

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'Hypothyroid'	(b) (4), (b) (6)	11 Sep 2020 11:28:22

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:26

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered '125'	(b) (4), (b) (6)	11 Sep 2020 11:28:22

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:26

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'ug (ug)' reason for change: Data Entry Samantha Wheeler	(b) (4)	13 Oct 2020 15:27:08
Error	(b) (4)	
User entered 'Other (OTHER)'	(b) (4), (b) (6)	11 Sep 2020 11:28:22

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:26

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User closed query 'Per CDM: Dose Unit is recorded as 'Other - MCG', however, please confirm if Unit can be selected from already available option 'ug'. If so, please update as appropriate, else clarify.	(b) (4), (b) (6)	19 Oct 2020 11:38:59
' (Site from DM).		
Query 'Per CDM: Dose Unit is recorded as 'Other - MCG', however, please confirm if Unit can be selected from already available option 'ug'. If so, please update as appropriate, else clarify.	Samantha Wheeler (b) (4)	13 Oct 2020 15:27:26
	(b) (4)	
' answered with 'updated' (Site from DM).		
User entered empty; reason for change Data Entry Error	Samantha Wheeler (b) (4)	13 Oct 2020 15:27:08
	(b) (4)	
User opened query 'Per CDM: Dose Unit is recorded as 'Other - MCG', however, please confirm if Unit can be selected from already available option 'ug'. If so, please update as appropriate, else clarify.	(b) (4), (b) (6)	18 Sep 2020 05:42:52
' (Site from DM).		
User entered 'mcg'	(b) (4), (b) (6)	11 Sep 2020 11:28:22

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:26

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'once daily (QD)'	(b) (4), (b) (6)	11 Sep 2020 11:28:22

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 11:28:22

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:26

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Sep 2020 11:28:22

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:26

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 11:28:22

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered '01 Sep 1983'	(b) (4), (b) (6)	11 Sep 2020 11:28:22

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 11:28:22

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:26

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 11:28:22

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:26

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 11:28:22

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 11:30:05
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Sep 2020 11:30:05
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 11:30:05
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 11:28:22
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 11:28:22

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 11:28:22

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 11:28:22

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 11:28:22

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:26

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LIOETHYRONINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 11:30:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 11:30:43
Data point term sent to Coder	System	11 Sep 2020 11:29:48
User entered 'Liothyronine'	(b) (4), (b) (6)	11 Sep 2020 11:29:45

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:26

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User closed query 'Per DM CLR: Note, Prophylaxis = YES. Please verify if this field should be updated as there is a corresponding condition recorded on Medical History page. If yes, please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 15:27:22
Query 'Per DM CLR: Note, Prophylaxis = YES. Please verify if this field should be updated as there is a corresponding condition recorded on Medical History page. If yes, please update eCRF as appropriate.' answered with 'updated' (Site from DM).	Samantha Wheeler (b) (4)	13 Oct 2020 15:26:37
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	13 Oct 2020 15:26:31
User opened query 'Per DM CLR: Note, Prophylaxis = YES. Please verify if this field should be updated as there is a corresponding condition recorded on Medical History page. If yes, please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 07:28:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 11:29:45

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:26

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'Hypothyroid'	(b) (4), (b) (6)	11 Sep 2020 11:29:45

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:26

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered '10'	(b) (4), (b) (6)	11 Sep 2020 11:29:45

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:26

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'ug (ug)' reason for change: Data Entry Samantha Wheeler	(b) (4)	13 Oct 2020 15:26:31
Error	(b) (4)	
User entered 'Other (OTHER)'	(b) (4), (b) (6)	11 Sep 2020 11:29:45

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:26

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User closed query 'Per CDM: Dose Unit is recorded as 'Other - MCG', however, please confirm if Unit can be selected from already available option 'ug'. If so, please update as appropriate, else clarify.	(b) (4), (b) (6)	19 Oct 2020 11:39:16
' (Site from DM). Query 'Per CDM: Dose Unit is recorded as 'Other - MCG', however, please confirm if Unit can be selected from already available option 'ug'. If so, please update as appropriate, else clarify.	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:26:45
' answered with 'updated' (Site from DM). User entered empty; reason for change Data Entry Error	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:26:31
User opened query 'Per CDM: Dose Unit is recorded as 'Other - MCG', however, please confirm if Unit can be selected from already available option 'ug'. If so, please update as appropriate, else clarify.	(b) (4), (b) (6)	18 Sep 2020 05:43:23
' (Site from DM). User entered 'mcg'	(b) (4), (b) (6)	11 Sep 2020 11:29:45

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:26

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'once daily (QD)'	(b) (4), (b) (6)	11 Sep 2020 11:29:45

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 11:29:45

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:26

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Sep 2020 11:29:45

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:26

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 11:29:45

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered '05 May 2020'	(b) (4), (b) (6)	11 Sep 2020 11:29:45

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 11:29:45

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:26

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 11:29:45

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:26

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 11:29:45

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 11:29:45

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 11:29:45

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 11:29:45

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 11:29:45

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:26

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: BUPROPION HYDROCHLORIDE, PRODUCTSYNONYM: WELLBUTRIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 11:32:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 11:32:43
Data point term sent to Coder	System	11 Sep 2020 11:31:49
User entered 'Wellbutrin'	(b) (4), (b) (6)	11 Sep 2020 11:31:19

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:26

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User closed query 'Per DM CLR: Note, Prophylaxis = YES. Please verify if this field should be updated as there is a corresponding condition recorded on Medical History page. If yes, please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 15:27:47
Query 'Per DM CLR: Note, Prophylaxis = YES. Please verify if this field should be updated as there is a corresponding condition recorded on Medical History page. If yes, please update eCRF as appropriate.' answered with 'updated' (Site from DM).	Samantha Wheeler (b) (4)	13 Oct 2020 15:25:54
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	13 Oct 2020 15:25:48
User opened query 'Per DM CLR: Note, Prophylaxis = YES. Please verify if this field should be updated as there is a corresponding condition recorded on Medical History page. If yes, please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 07:29:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 11:31:19

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:26

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'depression'	(b) (4), (b) (6)	11 Sep 2020 11:31:19

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:26

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered '150'	(b) (4), (b) (6)	11 Sep 2020 11:31:19

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:26

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'Other (OTHER)'	(b) (4), (b) (6)	11 Sep 2020 11:31:19

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:26

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'Unknown'	(b) (4), (b) (6)	11 Sep 2020 11:31:19

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:26

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'once daily (QD)'	(b) (4), (b) (6)	11 Sep 2020 11:31:19

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 11:31:19

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:26

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Sep 2020 11:31:19

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:26

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 11:31:19

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered '01 UNK 2000'	(b) (4), (b) (6)	11 Sep 2020 11:31:19

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 11:31:19

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:26

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 11:31:19

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:26

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 11:31:19

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 11:31:19

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 11:31:19

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 11:31:19

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 11:31:19

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:26

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 11:34:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 11:34:44
Data point term sent to Coder	System	11 Sep 2020 11:33:50
User entered 'Acetaminophen'	(b) (4), (b) (6)	11 Sep 2020 11:32:50

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:26

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 11:32:50

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:26

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User closed query 'Per DM CLR: Note there is no Medical History Condition or AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details (i.e. location of MUSCLE ACHES) to the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 15:26:03
Query 'Per DM CLR: Note there is no Medical History Condition or AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details (i.e. location of MUSCLE ACHES) to the appropriate eCRF. ' answered with 'updated' (Site from DM).	Samantha Wheeler (b) (4)	13 Oct 2020 15:25:41
User opened query 'Per DM CLR: Note there is no Medical History Condition or AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details (i.e. location of MUSCLE ACHES) to the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 07:29:53
User entered 'muscle aches'	(b) (4), (b) (6)	11 Sep 2020 11:32:50

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:26

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered '325'	(b) (4), (b) (6)	11 Sep 2020 11:32:50

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:26

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Sep 2020 11:32:50

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:26

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 11:32:50

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:26

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'once daily (QD)'	(b) (4), (b) (6)	11 Sep 2020 11:32:50

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 11:32:50

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:26

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Sep 2020 11:32:50

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:26

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 11:32:50

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered '05 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 11:32:50

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 11:32:50

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:26

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 11:32:50

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:26

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered '05 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 11:32:50

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'Yes (Y)' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	13 Oct 2020 15:25:36
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	11 Sep 2020 11:32:50

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 11:32:50

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 11:32:50

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 11:32:50

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:26

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 11:36:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 11:36:45
Data point term sent to Coder	System	11 Sep 2020 11:35:53
User entered 'Acetaminophen'	(b) (4), (b) (6)	11 Sep 2020 11:35:32

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:26

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 11:35:32

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:26

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User closed query 'Per DM CLR: Note there is no Medical History Condition or AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details (i.e. location of MUSCLE ACHES) to the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 15:32:32
Query 'Per DM CLR: Note there is no Medical History Condition or AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details (i.e. location of MUSCLE ACHES) to the appropriate eCRF. ' answered with 'updated' (Site from DM).	Samantha Wheeler (b) (4)	13 Oct 2020 15:25:26
User opened query 'Per DM CLR: Note there is no Medical History Condition or AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details (i.e. location of MUSCLE ACHES) to the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 07:30:05
User entered 'muscle aches'	(b) (4), (b) (6)	11 Sep 2020 11:35:32

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:26

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered '325'	(b) (4), (b) (6)	11 Sep 2020 11:35:32

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:26

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Sep 2020 11:35:32

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:26

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 11:35:32

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:26

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'once daily (QD)'	(b) (4), (b) (6)	11 Sep 2020 11:35:32

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 11:35:32

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:26

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Sep 2020 11:35:32

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:26

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 11:35:32

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered '07 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 11:35:32

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 11:35:32

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:26

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 11:35:32

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:26

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered '07 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 11:35:32

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'Yes (Y)' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	13 Oct 2020 15:25:21
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	11 Sep 2020 11:35:32

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 11:35:32

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 11:35:32

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 11:35:32

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:26

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 19:05:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	10 Nov 2020 19:05:53
Data point term sent to Coder Coding entries removed.	System Samantha Wheeler (b) (4)	10 Nov 2020 19:04:52 10 Nov 2020 19:04:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	21 Sep 2020 14:05:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Sep 2020 14:05:51
Data point term sent to Coder User entered 'acetaminophen'	System James Lovette (b) (4)	21 Sep 2020 14:04:10 21 Sep 2020 14:03:24

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:26

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'No (N)'	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:03:24

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:26

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the MUSCLE ACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of MUSCLE ACHES did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 16:37:14
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the MUSCLE ACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of MUSCLE ACHES did not meet the AE reporting criteria.' answered with 'updated to match AE for body aches' (Site from DM).	Samantha Wheeler (b) (4)	10 Nov 2020 19:04:12
User entered 'intermittent body aches' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	10 Nov 2020 19:04:02

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:26

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered '1'	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:03:24

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:26

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'capsule (CAPSULE)'	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:03:24

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:26

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered empty.	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:03:24

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:26

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'as needed (PRN)'	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:03:24

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered empty.	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:03:24

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:26

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'Oral (ORAL)'	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:03:24

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:26

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered empty.	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:03:24

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered '05 Sep 2020'	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:03:24

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered '0'	James Lovette (b) (4)	21 Sep 2020 14:03:24
	(b) (4)	

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:26

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'No (N)'	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:03:24

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:26

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered '07 Sep 2020'	James Lovette (b) (4)	21 Sep 2020 14:03:24
	(b) (4)	

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'No (N)'	James Lovette (b) (4) (b) (4)	21 Sep 2020 14:03:24

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 14:03:24

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 14:03:24

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 14:03:24

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:26

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 16:14:14
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 16:14:14
Data point term sent to Coder	System	13 Oct 2020 15:24:37
User entered 'omeprazole'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:24:17

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:26

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'No (N)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:24:17
	(b) (4)	

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:26

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'stomach ache'	Samantha Wheeler (b) (4)	13 Oct 2020 15:24:17
	(b) (4)	

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:26

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered '20'	Samantha Wheeler (b) (4)	13 Oct 2020 15:24:17
	(b) (4)	

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:26

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'mg (mg)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:24:17
	(b) (4)	

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:26

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered empty.	Samantha Wheeler (b) (4)	13 Oct 2020 15:24:17
	(b) (4)	

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:26

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'as needed (PRN)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:24:17
	(b) (4)	

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered empty.	Samantha Wheeler (b) (4)	13 Oct 2020 15:24:17
	(b) (4)	

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:26

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'Oral (ORAL)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:24:17
	(b) (4)	

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:26

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered empty.	Samantha Wheeler (b) (4)	13 Oct 2020 15:24:17
	(b) (4)	

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered '13 Sep 2020'	Samantha Wheeler (b) (4)	13 Oct 2020 15:24:17
	(b) (4)	

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered '0'	Samantha Wheeler (b) (4)	13 Oct 2020 15:24:17
	(b) (4)	

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:26

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'Yes (Y)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:24:17
	(b) (4)	

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:26

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered empty.	Samantha Wheeler (b) (4)	13 Oct 2020 15:24:17
	(b) (4)	

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'Yes (Y)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:24:17
	(b) (4)	

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 15:24:17

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 15:24:17

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 15:24:17

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:26

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, ATC: ANTIPROPULSIVES, ATC: ANTIPROPULSIVES, PRODUCT: LOPERAMIDE HYDROCHLORIDE, PRODUCTSYNONYM: IMODIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 16:05:20
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 16:05:20
Data point term sent to Coder	System	13 Oct 2020 15:25:38
User entered 'immodium'	Samantha Wheeler (b) (4) (b) (4)	13 Oct 2020 15:24:47

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:26

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'No (N)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:24:47
	(b) (4)	

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:26

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'stomach ache'	Samantha Wheeler (b) (4)	13 Oct 2020 15:24:47
	(b) (4)	

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:26

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered '2'	Samantha Wheeler (b) (4)	13 Oct 2020 15:24:47
	(b) (4)	

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:26

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'mg (mg)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:24:47
	(b) (4)	

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:26

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered empty.	Samantha Wheeler (b) (4)	13 Oct 2020 15:24:47
	(b) (4)	

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:26

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'as needed (PRN)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:24:47
	(b) (4)	

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered empty.	Samantha Wheeler (b) (4)	13 Oct 2020 15:24:47
	(b) (4)	

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:26

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'Oral (ORAL)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:24:47
	(b) (4)	

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:26

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered empty.	Samantha Wheeler (b) (4)	13 Oct 2020 15:24:47
	(b) (4)	

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:26

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered '13 Sep 2020'	Samantha Wheeler (b) (4)	13 Oct 2020 15:24:47
	(b) (4)	

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered '0'	Samantha Wheeler (b) (4)	13 Oct 2020 15:24:47
	(b) (4)	

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:26

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'Yes (Y)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:24:47
	(b) (4)	

US3762177

Folder: Concomitant Medication and Vaccination (1)

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Generated On: 26 Nov 2020 11:15:26

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered empty.	Samantha Wheeler (b) (4)	13 Oct 2020 15:24:47
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

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[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:31:48
User entered 'Yes (Y)'	Samantha Wheeler (b) (4)	13 Oct 2020 15:24:47
	(b) (4)	

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 15:24:47

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 15:24:47

US3762177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 15:24:47