

US3552273 (Prod: Saint Louis University)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:38:38

All time stamps listed in this document are displayed in GMT

US3552273

Form: Participant Creation

Generated On: 26 Nov 2020 09:38:38

[Participant ID](#)

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

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Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:38:38

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	01 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 09:38:38

Date of Birth (MMM yyyy)	(b) (6) 1967
Age	52
Age Units	YEARS
Age (Derived)	52
Sex	Female ☐ Male ☒
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:38:38

Date of Informed Consent (<i>dd MMM yyyy</i>)	01 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 09:38:38

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:38:38

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:38:38

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:38:38

Condition	GASTROESOPHAGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:38:38

Condition	GENERAL ANXIETY DISORDER
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 (4)

Generated On: 26 Nov 2020 09:38:38

Condition	SLEEP APNEA
Start date (dd MMM yyyy)	UN APR 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN APR 2009
Stop date completely unknown	False
Start Month and Year (derived)	APR 2009
Start Year (derived)	2009
Stop Month and Year (derived)	APR 2009
Stop Year (derived)	2009

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:38:38

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

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:38:38

Condition	BRONCHITIS
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 (7)

Generated On: 26 Nov 2020 09:38:38

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

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:38

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	01 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	12:00 (24 HR)
Vital Signs Date and Time (derived)	01 SEP 2020 12:00
Height (<i>xxx.x</i>)	69 in
Weight (<i>xxx.x</i>)	185.6 lb
BMI (<i>xxx.x</i>)	27.46564 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:38:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 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: Risk of Exposure

Generated On: 26 Nov 2020 09:38:38

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

FLEW 6 WEEKS AGO AND GOES TO THE (b) (6) TO SEE STAFF WITH MASK TWICE A MONTH FOR 2 DAYS, WORK PRIMARILY FROM HOME, GROCERY SHOPPING ONCE A WEEK, ONE ON ONE PERSON TRAINER IN PUBLIC GYM

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Folder: Screening

Form: Risk of Exposure

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Location and Living Circumstances Risk (check all that apply)

No Risk Identified	False
Resides in Nursing Home or Assisted Living Facility	False
Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	True
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:38:38

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	01 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 09:38:38

What was the date of randomization? (dd MMM yyyy) 01 SEP 2020

What was the participant's randomization number? 110608

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:38:38

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:38

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)	01 SEP 2020
Time of assessment (00:00-23:59)	12:00 (24 HR)
Vital Signs Date and Time (derived)	01 SEP 2020 12:00
Temperature (xxx.x)	97.2 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	24 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:38

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)	01 SEP 2020
Time of assessment (00:00-23:59)	14:07 (24 HR)
Vital Signs Date and Time (derived)	01 SEP 2020 14:07
Temperature (xxx.x)	97.9 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	124 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	22 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	177 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	105 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:38:38

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:38:38

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)	01 SEP 2020
What was the treatment time? (00:00-23:59)	13:37 (24 HR)
Treatment Date and Time (derived)	01 SEP 2020 13:37
Which arm was used to give treatment?	Left Arm ☒
	Right Arm ☐
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:38:38

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	01 SEP 2020
Collection time (<i>00:00-23:59</i>)	13:00 (24 HR)
Collection date and time (derived)	01 SEP 2020 13:00

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:38:38

Collection date (dd MMM yyyy)			01 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:12	01 SEP 2020 13:12
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:38:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:38:38

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

98.3 °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

01 SEP 2020 16:15

PC Open Date & Time

01 SEP 2020 13:57

PC Close Date & Time

01 SEP 2020 16:27

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:38:38

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 97.8 °F

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

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

PC Time Stamp	02 SEP 2020 10:56
PC Open Date & Time	01 SEP 2020 17:22
PC Close Date & Time	02 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:38:38

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

98.0 °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

02 SEP 2020 22:06

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:38:38

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

96.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 21:30

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:38:38

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

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 17:16

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(5)

Generated On: 26 Nov 2020 09:38:38

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

97.1 °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

05 SEP 2020 21:42

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:38:38

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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 18:51

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:38:38

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

07 SEP 2020 21:25

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:38:38

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

01 SEP 2020 16:13

PC Open Date & Time

01 SEP 2020 13:57

PC Close Date & Time

01 SEP 2020 16:27

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 10:56

PC Open Date & Time

01 SEP 2020 17:22

PC Close Date & Time

02 SEP 2020 11:59

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 22:05

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 18:59

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 17:16

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 17:02

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 SEP 2020 18:38

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 SEP 2020 17:19

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:38:38

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

No ☒

Yes ☐

PC Time stamp	01 SEP 2020 16:13
PC Open Date & Time	01 SEP 2020 13:57
PC Close Date & Time	01 SEP 2020 16:27

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:38:38

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

No ☒

Yes ☐

PC Time stamp	02 SEP 2020 10:06
PC Open Date & Time	01 SEP 2020 17:22
PC Close Date & Time	02 SEP 2020 11:59

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:38:38

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 ☒

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:38:38

Yes ☐	
PC Time stamp	02 SEP 2020 22:05
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:38:38

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 ☒

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:38:38

Yes ☐	
PC Time stamp	03 SEP 2020 18:59
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:38:38

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 ☒

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:38:38

Yes ☐	
PC Time stamp	04 SEP 2020 17:15
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:38:38

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 ☒

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:38:38

Yes ☐	
PC Time stamp	05 SEP 2020 17:02
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:38:38

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 ☒

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:38:38

Yes ☐	
PC Time stamp	06 SEP 2020 18:38
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:38:38

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 ☒

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:38:38

Yes ☐	
PC Time stamp	07 SEP 2020 17:19
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3552273

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☒

HEADACHE

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 ☐

PC Time Stamp 08 SEP 2020 15:50

PC Open Date & Time 08 SEP 2020 12:00

PC Close Date & Time 09 SEP 2020 11:59

US3552273

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	08 SEP 2020 15:50
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3552273

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552273

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552273

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:38

Was Contact Attempted?

Yes ☒

No ☐

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

15 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552273

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552273

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:38

Was Contact Attempted?

Yes ☒

No ☐

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

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552273

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552273

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:38:38

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	28 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:38

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	28 SEP 2020
Time of assessment (00:00-23:59)	09:02 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 09:02
Temperature (xxx.x)	98.1 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	140 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	162 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	98 mmHg
Diastolic Blood Pressure units	MMHG

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:38

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	

US3552273

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:38:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 SEP 2020

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

US3552273

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:38:38

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 ANXIETY

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? _____

US3552273

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:38:38

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

28 SEP 2020

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

09:30 (24 HR)

Collection date and time (derived)

28 SEP 2020 09:30

US3552273

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:38:38

Collection date (dd MMM yyyy)			28 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:32	28 SEP 2020 09:32
Nasopharyngeal Swab 2	No		

US3552273

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552273

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552273

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552273

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552273

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552273

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552273

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552273

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:38:38

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	03 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3552273

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:38

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	03 NOV 2020
Time of assessment (<i>00:00-23:59</i>)	14:05 (24 HR)
Vital Signs Date and Time (derived)	03 NOV 2020 14:05
Temperature (<i>xxx.x</i>)	97.5 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	99 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3552273

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:38:38

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.

US3552273

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:38:38

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	03 NOV 2020
Collection time (<i>00:00-23:59</i>)	14:12 (24 HR)
Collection date and time (derived)	03 NOV 2020 14:12

US3552273

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552273

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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	01 NOV 2020 08:14:43
Patient Cloud Open Date & Time	01 NOV 2020 00:01
Patient Cloud Close Date & Time	05 NOV 2020 23:59

US3552273

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 11:40:37

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3552273

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 NOV 2020 07:05:38
Patient Cloud Open Date & Time	15 NOV 2020 00:01
Patient Cloud Close Date & Time	19 NOV 2020 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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 2020 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2020 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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 2020 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2020 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2020 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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	22 NOV 2020 14:02:18
Patient Cloud Open Date & Time	19 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2020 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2020 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

14 DEC 2020 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2020 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

28 DEC 2020 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2021 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2021 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2021 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2021 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2021 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2021 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2021 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2021 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2021 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2021 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2021 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2021 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2021 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2021 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2021 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2021 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2021 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2021 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2021 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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 SEP 2021 00:01

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27 SEP 2021 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2021 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2021 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

20 DEC 2021 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

27 DEC 2021 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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03 JAN 2022 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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

Date and time of submission

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10 JAN 2022 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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

Date and time of submission

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17 JAN 2022 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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

Date and time of submission

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20 JAN 2022 00:01

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24 JAN 2022 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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

Date and time of submission

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10 MAR 2022 00:01

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14 MAR 2022 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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21 MAR 2022 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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28 MAR 2022 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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04 APR 2022 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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

Date and time of submission

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07 JUL 2022 00:01

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11 JUL 2022 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUL 2022 00:01

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18 JUL 2022 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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21 JUL 2022 00:01

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25 JUL 2022 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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01 AUG 2022 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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08 AUG 2022 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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15 AUG 2022 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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18 AUG 2022 00:01

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22 AUG 2022 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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25 AUG 2022 00:01

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29 AUG 2022 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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05 SEP 2022 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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12 SEP 2022 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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15 SEP 2022 00:01

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19 SEP 2022 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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 SEP 2022 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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03 OCT 2022 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2022 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

24 OCT 2022 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2022 23:59

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 ☐

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2022 23:59

US3552273

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552273

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:38

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3552273

Folder: Covid-19 Assessment 03 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:38:38

Date of Contact

Time of Contact

Date and Time of Contact (derived)

Type of Contact

Clinic Visit - Scheduled ☐

Clinical Visit - Unscheduled ☐

Safety Call ☐

Convalescent Tele-visit ☐

Has the subject reported symptoms of SARS-COV-2?

Yes ☐

No ☐

US3552273

Folder: Covid-19 Assessment 03 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:38:38

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3552273

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:38:38

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3552273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:38

AEID	
Adverse event	WORSENING HYPERTENSION
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)	01 SEP 2020
Start time (00:00-23:59)	14:07 (24 HR)
AE start date and time (derived)	01 SEP 2020 14:07
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

v6.020 DTW (1102)

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US3552273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:38

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

US3552273

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:38

AEID	
Adverse event	TACHYCARDIA
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)	01 SEP 2020
Start time (00:00-23:59)	14:07 (24 HR)
AE start date and time (derived)	01 SEP 2020 14:07
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
v6.020 DTW (1102)	
308 of 1424	

US3552273

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:38

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

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:38:38

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

Yes ☒

No ☐

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

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:38:38

Name of Medication	LISINOPRIL/HYDROCHLOROTHIAZIDE
Prophylaxis	Yes ☐ No ☒
Indication	HYPERTENSION
Dose per administration	20 / 25
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 ☐

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:38:38

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 1990
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	☒

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:38:38

Name of Medication	OMEPRAZOLE
Prophylaxis	Yes ☐ No ☒
Indication	GASTROESOPHAGEAL REFLUX DISEASE
Dose per administration	40
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:38:38

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

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:38:38

Name of Medication	ALPRAZOLAM
Prophylaxis	Yes ☐ No ☒
Indication	ANXIETY AND TACHYCARDIA
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 ☐

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:38:38

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 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)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:38:38

Name of Medication	DOSCOVY
Prophylaxis	Yes ☒ No ☐
Indication	HIV PROPHYLAXIS
Dose per administration	200/25
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 ☐

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:38:38

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

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:38:38

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

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:38:38

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN MAR 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	☒

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:38:38

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

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:38:38

	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)		16 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		16 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)		802 ☐
		803 ☐
		804 ☐

US3552273

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:38:38

Were any concomitant procedures performed?

Yes ☐

No ☐

If yes, please complete Concomitant Procedures form.

US3552273

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:38:38

Date of dosing discontinuation (dd MMM yyyy)

28 SEP 2020

Primary reason for dosing discontinuation

AE (specify) ☒

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

AE #1

US3552273

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:38:38

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

US3552273 (Prod: Saint Louis University)

US3552273

Form: Participant Creation

Generated On: 26 Nov 2020 09:38:38

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3552273'	RWS_ENDPOINT ENDPOINT (b) (4) 	01 Sep 2020 18:14:25

US3552273

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:38:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:26:03

US3552273

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered '01 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	01 Sep 2020 18:14:27

US3552273

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:26:03

US3552273

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:38:38

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	02 Sep 2020 13:26:03

US3552273

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered (b) (6) 1967'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	01 Sep 2020 18:14:28

US3552273

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:38:38

[Age](#)

Audit	User	Time (GMT)
User entered '52'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:26:31

US3552273

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:38:38

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	02 Sep 2020 13:26:31

US3552273

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:38:38

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '52'	System	01 Sep 2020 18:14:53

US3552273

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:38:38

[Sex](#)

Audit	User	Time (GMT)
User entered 'Male (M)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:26:31

US3552273

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:38:38

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Stanley Doublin (b) (4)	02 Sep 2020 13:26:31

US3552273

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:38:38

[White](#)

Audit	User	Time (GMT)
User entered '1'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:26:31

US3552273

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:38:38

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:26:31

US3552273

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:38:38

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:26:31

US3552273

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:38:38

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:26:31

US3552273

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:38:38

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:26:31

US3552273

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:38:38

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:26:31

US3552273

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:38:38

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:26:31

US3552273

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:38:38

[Unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:26:31

US3552273

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:38:38

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:26:31

US3552273

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered '01 Sep 2020' reason for change: Data Entry Error	Stanley Dublin (b) (4)	10 Nov 2020 20:08:27
User entered '1 Sep 2020'	(b) (4), (b) (6)	01 Sep 2020 18:14:53

US3552273

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered 'Sep 2020'	System	01 Sep 2020 18:14:53

US3552273

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered '2020'	System	01 Sep 2020 18:14:53

US3552273

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:38:38

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 3 (3)'	(b) (4), (b) (6)	01 Sep 2020 18:14:53

US3552273

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 18:14:53

US3552273

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 18:14:53

US3552273

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:38:38

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 18:14:53

US3552273

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:38:38

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 18:14:53

US3552273

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:38:38

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	01 Sep 2020 18:14:27

US3552273

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:38:38

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:15:05

US3552273

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 18:15:05

US3552273

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:38:38

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:26:40

US3552273

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:38:38

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 13:27:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 13:27:43
Data point term sent to Coder	System	02 Sep 2020 13:27:21
User entered 'hypertension'	Stanley Doublin (b) (4)	02 Sep 2020 13:27:19

US3552273

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered 'un UNK 1990'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:27:19

US3552273

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:38:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:27:19

US3552273

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:38:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:27:19

US3552273

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:27:19

US3552273

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:38:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:27:19

US3552273

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered 'Jan 1990'	System	02 Sep 2020 13:27:19

US3552273

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered '1990'	System	02 Sep 2020 13:27:19

US3552273

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 13:27:19

US3552273

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 13:27:19

US3552273

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:38:38

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 13:28:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 13:28:48
Data point term sent to Coder	System	02 Sep 2020 13:28:23
User entered 'gastroesophageal reflux disease'	Stanley Doublin (b) (4)	02 Sep 2020 13:27:43

US3552273

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered 'un UNK 2019'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:27:43

US3552273

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:38:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:27:43

US3552273

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:38:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:27:43

US3552273

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:27:43

US3552273

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:38:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:27:43

US3552273

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	02 Sep 2020 13:27:43

US3552273

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered '2019'	System	02 Sep 2020 13:27:43

US3552273

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 13:27:43

US3552273

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 13:27:43

US3552273

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:38:38

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety disorders NEC, PT: Generalised anxiety disorder, LLT: Generalized anxiety disorder - version MedDRA\23.0.	Coder Import (b) (4)	20 Oct 2020 14:10:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	20 Oct 2020 14:10:39
Data point term sent to Coder	System	20 Oct 2020 14:09:45
Coding entries removed.	Heather Douds (b) (4)	20 Oct 2020 14:09:02
User entered 'General ANXIETY disorder' reason for change: Data Entry Error	(b) (4)	
User entered 'General ANXIETY disorder' reason for change: Data Entry Error	Heather Douds (b) (4)	20 Oct 2020 14:09:02
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	02 Sep 2020 13:56:44
Data point term sent to Coder	(b) (4)	
User entered 'ANXIETY' reason for change: Data Entry Error	System	02 Sep 2020 13:55:24
Data point term sent to Coder	Stanley Doublin (b) (4)	02 Sep 2020 13:54:38
User entered 'moderate anxiety'	(b) (4)	
	System	02 Sep 2020 13:28:26
	Stanley Doublin (b) (4)	02 Sep 2020 13:28:03
	(b) (4)	

US3552273

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered 'un UNK 2000'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:28:03

US3552273

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:38:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:28:03

US3552273

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:38:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:28:03

US3552273

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:28:03

US3552273

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:38:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:28:03

US3552273

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	02 Sep 2020 13:28:03

US3552273

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered '2000'	System	02 Sep 2020 13:28:03

US3552273

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 13:28:03

US3552273

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 13:28:03

US3552273

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:38:38

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Sleep apnea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 13:28:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 13:28:47
Data point term sent to Coder	System	02 Sep 2020 13:28:27
User entered 'sleep apnea'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:28:23

US3552273

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered 'un Apr 2009'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:28:23

US3552273

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:38:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:28:23

US3552273

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:38:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:28:23

US3552273

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered 'un Apr 2009'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:28:23

US3552273

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:38:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:28:23

US3552273

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered 'Apr 2009'	System	02 Sep 2020 13:28:23

US3552273

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered '2009'	System	02 Sep 2020 13:28:23

US3552273

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered 'Apr 2009'	System	02 Sep 2020 13:28:23

US3552273

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered '2009'	System	02 Sep 2020 13:28:23

US3552273

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:38:38

[Condition](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please specify the laterality of RENAL CALCULI (left, right, bilateral). Review and update MH condition as appropriate and ensure update is reconciled with any corresponding ConMed/AE entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 12:49:29
Query 'Per DM CLR: Please specify the laterality of RENAL CALCULI (left, right, bilateral). Review and update MH condition as appropriate and ensure update is reconciled with any corresponding ConMed/AE entries, if applicable.' answered with 'Unknown, medical records not available as we are not a clinical site. Con meds within 28 days of 1st vaccination are recorded as per protocol.' (Site from DM).	Heather Douds (b) (4)	06 Oct 2020 14:46:19
User opened query 'Per DM CLR: Please specify the laterality of RENAL CALCULI (left, right, bilateral). Review and update MH condition as appropriate and ensure update is reconciled with any corresponding ConMed/AE entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 03:51:14
User coded data point as SOC: Renal and urinary disorders, HLGT: Urolithiasis, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Renal calculi - version MedDRA\23.0.	Coder Import (b) (4)	02 Sep 2020 13:29:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	02 Sep 2020 13:29:49
Data point term sent to Coder	System	02 Sep 2020 13:29:29
User entered 'renal calculi'	Stanley Doublin (b) (4)	02 Sep 2020 13:29:07

US3552273

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered 'un UNK 2003'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:29:07

US3552273

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:38:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:29:07

US3552273

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:38:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:29:07

US3552273

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered 'un UNK 2003'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:29:07

US3552273

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:38:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:29:07

US3552273

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered 'Jan 2003'	System	02 Sep 2020 13:29:07

US3552273

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered '2003'	System	02 Sep 2020 13:29:07

US3552273

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered 'Jan 2003'	System	02 Sep 2020 13:29:07

US3552273

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered '2003'	System	02 Sep 2020 13:29:07

US3552273

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:38:38

[Condition](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 06:56:27
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'Con meds within 28 days of 1st vaccination are recorded as per protocol. ' (Site from DM).	Heather Douds (b) (4)	06 Oct 2020 14:46:40
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 03:06:33
Data hard unlocked.	(b) (4), (b) (6)	06 Oct 2020 03:06:25
Data hard locked.	(b) (4), (b) (6)	06 Oct 2020 03:06:22
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Bronchitis, LLT: Bronchitis - version MedDRA\23.0.	Coder Import (b) (4)	02 Sep 2020 13:56:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	02 Sep 2020 13:56:45
Data point term sent to Coder	System	02 Sep 2020 13:55:27
User entered 'BRONCHITIS' reason for change:	Stanley Dublin (b) (4)	02 Sep 2020 13:55:26
Data Entry Error	(b) (4)	
Data point term sent to Coder	System	02 Sep 2020 13:31:34
User entered 'upper respiratory or infections bronchitis'	Stanley Dublin (b) (4)	02 Sep 2020 13:30:50

US3552273

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered 'un UNK 2000'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:30:50

US3552273

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:38:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:30:50

US3552273

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:38:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:30:50

US3552273

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:30:50

US3552273

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:38:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:30:50

US3552273

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	02 Sep 2020 13:30:50

US3552273

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered '2000'	System	02 Sep 2020 13:30:50

US3552273

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 13:30:50

US3552273

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 13:30:50

US3552273

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:38:38

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLT: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Lithotripsy, LLT: Lithotripsy - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 17:32:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 17:32:54
Data point term sent to Coder	System	02 Sep 2020 17:31:57
User entered 'lithotripsy'	Heather Douds (b) (4)	02 Sep 2020 17:31:12

US3552273

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered 'un UNK 2003'	Heather Douds (b) (4) (b) (4)	02 Sep 2020 17:31:12

US3552273

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:38:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Heather Douds (b) (4) (b) (4)	02 Sep 2020 17:31:12

US3552273

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:38:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Heather Douds (b) (4) (b) (4)	02 Sep 2020 17:31:12

US3552273

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered 'un UNK 2003'	Heather Douds (b) (4) (b) (4)	02 Sep 2020 17:31:12

US3552273

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:38:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Heather Douds (b) (4) (b) (4)	02 Sep 2020 17:31:12

US3552273

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered 'Jan 2003'	System	02 Sep 2020 17:31:12

US3552273

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered '2003'	System	02 Sep 2020 17:31:12

US3552273

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered 'Jan 2003'	System	02 Sep 2020 17:31:12

US3552273

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered '2003'	System	02 Sep 2020 17:31:12

US3552273

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:31:35

US3552273

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered '01 Sep 2020' reason for change: Data Entry Error	Stanley Dublin (b) (4)	10 Nov 2020 20:08:40
User entered '1 Sep 2020'	Stanley Dublin (b) (4)	02 Sep 2020 13:31:35

US3552273

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered '12:00'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:31:35

US3552273

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	10 Nov 2020 20:08:40
User entered '1 Sep 2020 12:00'	System	02 Sep 2020 13:31:35

US3552273

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered '69' in	Stanley Dublin (b) (4)	02 Sep 2020 13:31:35
DataPoint set to visible.	(b) (4) System	01 Sep 2020 18:15:05

US3552273

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered '185.6' lb	Stanley Dublin (b) (4)	02 Sep 2020 13:31:35
DataPoint set to visible.	(b) (4) System	01 Sep 2020 18:15:05

US3552273

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered '27.46564'	System	02 Sep 2020 13:31:35
DataPoint set to visible.	System	01 Sep 2020 18:15:05

US3552273

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:38

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	02 Sep 2020 13:31:35
DataPoint set to visible.	System	01 Sep 2020 18:15:05

US3552273

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:31:35

US3552273

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:38

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:31:35

US3552273

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:38

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:31:35

US3552273

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:31:35

US3552273

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:38

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	02 Sep 2020 13:31:35

US3552273

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:31:35

US3552273

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	02 Sep 2020 13:31:35

US3552273

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:31:35

US3552273

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Sep 2020 13:31:35

US3552273

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:31:35

US3552273

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Sep 2020 13:31:35

US3552273

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:38:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Stanley Dublin (b) (4)	10 Nov 2020 20:11:50
User entered 'No (N)'	Stanley Dublin (b) (4)	02 Sep 2020 13:31:46

US3552273

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered '01 Sep 2020' reason for change: Data Entry Error	Stanley Dublin (b) (4)	10 Nov 2020 20:11:50
User entered empty.	Stanley Dublin (b) (4)	02 Sep 2020 13:31:46

US3552273

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:35:01

US3552273

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:35:01

US3552273

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:38

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)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:35:01

US3552273

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:35:01

US3552273

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:35:01

US3552273

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:35:01

US3552273

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:38

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)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:35:01

US3552273

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:38

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)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:35:01

US3552273

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:35:01

US3552273

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:38

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)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:35:01

US3552273

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:38

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)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:35:01

US3552273

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:38

Other

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:35:01

US3552273

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:38

[Specify](#)

Audit	User	Time (GMT)
User entered 'flew 6 weeks ago and goes to the (b) (6) Stanley Dublin (b) (4) (b) (6) to see staff with mask twice a month for 2 days, (b) (4) work primarily from home, grocery shopping once a week, one on one person trainer in public gym'		02 Sep 2020 13:35:01

US3552273

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:38

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:35:01

US3552273

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:38

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:35:01

US3552273

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:38

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'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:35:01

US3552273

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:35:01

US3552273

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:38

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'	Stanley Doublin (b) (4)	02 Sep 2020 13:35:01
	(b) (4)	

US3552273

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered '1'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:35:01

US3552273

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:38

Other

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:35:01

US3552273

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:38:38

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:35:01

US3552273

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:38:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:35:13

US3552273

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered '01 Sep 2020' reason for change: Data Entry Error	Stanley Dublin (b) (4)	10 Nov 2020 20:12:01
User entered '1 Sep 2020'	Stanley Dublin (b) (4)	02 Sep 2020 13:35:13

US3552273

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:35:13

US3552273

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:38:38

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	02 Sep 2020 13:35:13

US3552273

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered '01 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	01 Sep 2020 18:14:32

US3552273

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:38:38

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
User entered '110608'	RWS_ENDPOINT ENDPOINT (b) (4) 	01 Sep 2020 18:14:32

US3552273

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	01 Sep 2020 18:14:32

US3552273

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:38:38

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)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:35:23

US3552273

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:35:23

US3552273

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:35:23

US3552273

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:35:23

US3552273

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:38:38

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:35:23

US3552273

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4)	21 Sep 2020 17:45:52
Amendment Manager: DataPoint set to visible.	(b) (4)	19 Sep 2020 08:59:45
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:59:44

US3552273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:38:38

[Height](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:39:50

US3552273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:38:38

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:39:50

US3552273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:38:38

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:39:50

US3552273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:38:38

[Weight](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:39:50

US3552273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:38

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Stanley Dublin (b) (4)	02 Sep 2020 13:39:50
	(b) (4)	

US3552273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:39:50

US3552273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered '01 Sep 2020' reason for change: Data Entry Error	Stanley Dublin (b) (4)	10 Nov 2020 20:12:16
User entered '1 Sep 2020'	Stanley Dublin (b) (4)	02 Sep 2020 13:39:50

US3552273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered '12:00'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:39:50

US3552273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	10 Nov 2020 20:12:16
User entered '1 Sep 2020 12:00'	System	02 Sep 2020 13:39:50

US3552273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:38

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.2' F	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:39:50

US3552273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:38

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:39:50

US3552273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:38

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:39:50

US3552273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '80'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:39:50

US3552273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:38

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	02 Sep 2020 13:39:50

US3552273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered '24'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:39:50

US3552273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	02 Sep 2020 13:39:50

US3552273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered '146'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:39:50

US3552273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Sep 2020 13:39:50

US3552273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered '77'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:39:50

US3552273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Sep 2020 13:39:50

US3552273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:38:38

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:39:50

US3552273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:38:38

[Weight](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:39:50

US3552273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:38

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:40:27

US3552273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:40:27

US3552273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered '01 Sep 2020' reason for change: Data Entry Error	Stanley Dublin (b) (4)	10 Nov 2020 20:12:16
User entered '1 Sep 2020'	Stanley Dublin (b) (4)	02 Sep 2020 13:40:27

US3552273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered '14:07'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:40:27

US3552273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered '01 Sep 2020 14:07'	System	10 Nov 2020 20:12:16
User entered '1 Sep 2020 14:07'	System	02 Sep 2020 13:40:27

US3552273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:38

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.9' F	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:40:27

US3552273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:38

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:40:27

US3552273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:38

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:40:27

US3552273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '124'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:40:27

US3552273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:38

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	02 Sep 2020 13:40:27

US3552273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered '22'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:40:27

US3552273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	02 Sep 2020 13:40:27

US3552273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	03 Sep 2020 18:17:07
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Clinically significant, AE entered' (Site from System).	Heather Douds (b) (4)	03 Sep 2020 14:57:59
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	02 Sep 2020 13:40:27
User entered '177'	Stanley Dublin (b) (4)	02 Sep 2020 13:40:27

US3552273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Sep 2020 13:40:27

US3552273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	03 Sep 2020 18:17:15
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Clinically significant, AE entered' (Site from System).	Heather Douds (b) (4)	03 Sep 2020 14:57:57
User opened query 'Diastolic Blood Pressure reported System is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		02 Sep 2020 13:40:27
User entered '105'	Stanley Dublin (b) (4)	02 Sep 2020 13:40:27

US3552273

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Sep 2020 13:40:27

US3552273

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:38:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:42:02

US3552273

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:38:38

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:42:02

US3552273

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:38:38

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 18:42:39

US3552273

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:38:38

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 18:42:39

US3552273

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:38:38

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)	01 Sep 2020 18:42:39

US3552273

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:38:38

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	01 Sep 2020 18:42:39

US3552273

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:38:38

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020' reason for change: Data Entry Error	Stanley Dublin (b) (4)	10 Nov 2020 20:12:28
User entered '1 Sep 2020'	(b) (4), (b) (6)	01 Sep 2020 18:42:39

US3552273

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:38:38

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '13:37'	(b) (4), (b) (6)	01 Sep 2020 18:42:39

US3552273

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:38:38

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 13:37'	System	10 Nov 2020 20:12:28
User entered '1 Sep 2020 13:37'	System	01 Sep 2020 18:42:39

US3552273

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:38:38

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	01 Sep 2020 18:42:39

US3552273

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:38:38

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	01 Sep 2020 18:42:39

US3552273

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:38:38

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	01 Sep 2020 18:42:39

US3552273

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:38:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:42:15

US3552273

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered '01 Sep 2020' reason for change: Data Entry Error	Stanley Dublin (b) (4)	10 Nov 2020 20:12:35
User entered '1 Sep 2020'	Stanley Dublin (b) (4)	02 Sep 2020 13:42:15

US3552273

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:38:38

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '13:00'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:42:15

US3552273

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:38:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 13:00'	System	10 Nov 2020 20:12:35
User entered '1 Sep 2020 13:00'	System	02 Sep 2020 13:42:15

US3552273

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered '01 Sep 2020' reason for change: Data Entry Error	Stanley Dublin (b) (4)	10 Nov 2020 20:12:42
User entered '1 Sep 2020'	Stanley Dublin (b) (4)	02 Sep 2020 13:42:51

US3552273

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:38:38

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Stanley Dublin (b) (4)	02 Sep 2020 13:42:51

US3552273

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:38:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:42:51

US3552273

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:38:38

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered '13:12'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:42:51

US3552273

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:38:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 13:12'	System	10 Nov 2020 20:12:42
User entered '1 Sep 2020 13:12'	System	02 Sep 2020 13:42:51

US3552273

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:38:38

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Stanley Dublin (b) (4)	02 Sep 2020 13:42:51

US3552273

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:38:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:42:51

US3552273

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:38:38

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:42:51

US3552273

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:38:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 13:42:51

US3552273

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:38:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	08 Sep 2020 17:30:46

US3552273

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:38:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 17:30:46

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 18:42:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:38:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-01T16:14:31', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '9e144a6c-7d0d-4a80-b086-a2bc92d1a199'	System	01 Sep 2020 21:15:08
User entered 'Yes (Y)'	System	01 Sep 2020 21:15:08

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:38:38

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-01T16:14:59', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '9e144a6c-7d0d-4a80-b086-a2bc92d1a199'	System	01 Sep 2020 21:15:08
User entered '98.3'	System	01 Sep 2020 21:15:08

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-01T16:15:02', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '9e144a6c-7d0d-4a80-b086-a2bc92d1a199'	System	01 Sep 2020 21:15:08
User entered 'No (N)'	System	01 Sep 2020 21:15:08

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:38:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-01T16:15:05', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '9e144a6c-7d0d-4a80-b086-a2bc92d1a199'	System	01 Sep 2020 21:15:08
User entered '01 Sep 2020 16:15'	System	01 Sep 2020 21:15:08

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:38:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 13:57'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:38:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 16:27'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 18:42:39
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:38:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T10:55:42', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'a0aaf5e0-b661-4e04-add7-9dc935f588e4'	System	02 Sep 2020 15:56:05
User entered 'Yes (Y)'	System	02 Sep 2020 15:56:05

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:38:38

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T10:55:53', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'a0aaf5e0-b661-4e04-add7-9dc935f588e4'	System	02 Sep 2020 15:56:05
User entered '97.8'	System	02 Sep 2020 15:56:05

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T10:55:58', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'a0aaf5e0-b661-4e04-add7-9dc935f588e4'	System	02 Sep 2020 15:56:05
User entered 'No (N)'	System	02 Sep 2020 15:56:05

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:38:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T10:56:01', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'a0aaf5e0-b661-4e04-add7-9dc935f588e4'	System	02 Sep 2020 15:56:05
User entered '02 Sep 2020 10:56'	System	02 Sep 2020 15:56:05

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:38:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 17:22'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:38:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 18:42:39
User entered 'Day 2'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:38:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T22:05:37', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'd4eb0921-73d7-420e-9db8-a58ccd11d6f2'	System	03 Sep 2020 03:06:04
User entered 'Yes (Y)'	System	03 Sep 2020 03:06:04

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:38:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T22:05:55', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'd4eb0921-73d7-420e-9db8-a58ccd11d6f2'	System	03 Sep 2020 03:06:04
User entered '98.0'	System	03 Sep 2020 03:06:04

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T22:05:58', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'd4eb0921-73d7-420e-9db8-a58ccd11d6f2'	System	03 Sep 2020 03:06:04
User entered 'No (N)'	System	03 Sep 2020 03:06:04

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:38:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T22:06:01', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'd4eb0921-73d7-420e-9db8-a58ccd11d6f2'	System	03 Sep 2020 03:06:04
User entered '02 Sep 2020 22:06'	System	03 Sep 2020 03:06:04

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:38:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:38:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 18:42:39
User entered 'Day 3'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:38:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-03T21:28:07', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '4e787de5-b7f1-4824-9997-77e688290534'	System	04 Sep 2020 02:30:28
User entered 'Yes (Y)'	System	04 Sep 2020 02:30:28

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:38:38

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-03T21:30:18', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '4e787de5-b7f1-4824-9997-77e688290534'	System	04 Sep 2020 02:30:28
User entered '96.0'	System	04 Sep 2020 02:30:28

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-03T21:30:22', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '4e787de5-b7f1-4824-9997-77e688290534'	System	04 Sep 2020 02:30:28
User entered 'No (N)'	System	04 Sep 2020 02:30:28

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:38:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-03T21:30:25', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '4e787de5-b7f1-4824-9997-77e688290534'	System	04 Sep 2020 02:30:28
User entered '03 Sep 2020 21:30'	System	04 Sep 2020 02:30:28

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:38:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:38:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 18:42:39
User entered 'Day 4'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:38:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-04T17:16:13', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '1bbca0fa-d8e0-44cb-ad93-e767fa0eb3f4'	System	04 Sep 2020 22:16:37
User entered 'Yes (Y)'	System	04 Sep 2020 22:16:37

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:38:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-04T17:16:28', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '1bbca0fa-d8e0-44cb-ad93-e767fa0eb3f4'	System	04 Sep 2020 22:16:37
User entered '98.4'	System	04 Sep 2020 22:16:37

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-04T17:16:33', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '1bbca0fa-d8e0-44cb-ad93-e767fa0eb3f4'	System	04 Sep 2020 22:16:37
User entered 'No (N)'	System	04 Sep 2020 22:16:37

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:38:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-04T17:16:35', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '1bbca0fa-d8e0-44cb-ad93-e767fa0eb3f4'	System	04 Sep 2020 22:16:37
User entered '04 Sep 2020 17:16'	System	04 Sep 2020 22:16:37

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:38:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:38:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 18:42:39
User entered 'Day 5'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:38:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-05T21:42:15', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '84c5e8eb-cf2b-43bc-a6c0-bd3eb0b27624'	System	06 Sep 2020 02:42:26
User entered 'Yes (Y)'	System	06 Sep 2020 02:42:26

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:38:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-05T21:42:19', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '84c5e8eb-cf2b-43bc-a6c0-bd3eb0b27624'	System	06 Sep 2020 02:42:26
User entered '97.1'	System	06 Sep 2020 02:42:26

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-05T21:42:22', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '84c5e8eb-cf2b-43bc-a6c0-bd3eb0b27624'	System	06 Sep 2020 02:42:26
User entered 'No (N)'	System	06 Sep 2020 02:42:26

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:38:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-05T21:42:24', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '84c5e8eb-cf2b-43bc-a6c0-bd3eb0b27624'	System	06 Sep 2020 02:42:26
User entered '05 Sep 2020 21:42'	System	06 Sep 2020 02:42:26

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:38:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:38:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 18:42:39
User entered 'Day 6'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:38:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-06T18:51:42', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '3b4619fb-6436-4046-82ce-b1c7ee2a685f'	System	06 Sep 2020 23:52:00
User entered 'Yes (Y)'	System	06 Sep 2020 23:52:00

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:38:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-06T18:51:53', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '3b4619fb-6436-4046-82ce-b1c7ee2a685f'	System	06 Sep 2020 23:52:00
User entered '97.8'	System	06 Sep 2020 23:52:00

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-06T18:51:56', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '3b4619fb-6436-4046-82ce-b1c7ee2a685f'	System	06 Sep 2020 23:52:00
User entered 'No (N)'	System	06 Sep 2020 23:52:00

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:38:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-06T18:51:58', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '3b4619fb-6436-4046-82ce-b1c7ee2a685f'	System	06 Sep 2020 23:52:00
User entered '06 Sep 2020 18:51'	System	06 Sep 2020 23:52:00

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:38:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:38:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 18:42:39
User entered 'Day 7'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:38:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-07T21:24:54', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'c38bb5c6-06b4-4d4f-bc21-84b7fb156a3f'	System	08 Sep 2020 02:25:09
User entered 'Yes (Y)'	System	08 Sep 2020 02:25:09

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:38:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-07T21:24:59', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'c38bb5c6-06b4-4d4f-bc21-84b7fb156a3f'	System	08 Sep 2020 02:25:09
User entered '98.0'	System	08 Sep 2020 02:25:09

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-07T21:25:03', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'c38bb5c6-06b4-4d4f-bc21-84b7fb156a3f'	System	08 Sep 2020 02:25:09
User entered 'No (N)'	System	08 Sep 2020 02:25:09

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:38:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-07T21:25:05', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'c38bb5c6-06b4-4d4f-bc21-84b7fb156a3f'	System	08 Sep 2020 02:25:09
User entered '07 Sep 2020 21:25'	System	08 Sep 2020 02:25:09

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:38:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:38:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 18:42:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:38:38

[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 (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-01T16:13:39', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'ff211bff-c633-489d-bc16-1e3cdd0b1e75'	System	01 Sep 2020 21:13:57
User entered 'None (1)'	System	01 Sep 2020 21:13:57

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:38:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-01T16:13:43', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'ff211bff-c633-489d-bc16-1e3cdd0b1e75'	System	01 Sep 2020 21:13:57
User entered 'No (N)'	System	01 Sep 2020 21:13:57

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-01T16:13:46', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'ff211bff-c633-489d-bc16-1e3cdd0b1e75'	System	01 Sep 2020 21:13:57
User entered 'No (N)'	System	01 Sep 2020 21:13:57

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:38:38

[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 (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-01T16:13:50', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'ff211bff-c633-489d-bc16-1e3cdd0b1e75'	System	01 Sep 2020 21:13:57
User entered 'None (1)'	System	01 Sep 2020 21:13:57

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:38:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-01T16:13:53', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'ff211bff-c633-489d-bc16-1e3cdd0b1e75'	System	01 Sep 2020 21:13:57
User entered '01 Sep 2020 16:13'	System	01 Sep 2020 21:13:57

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:38:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 13:57'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:38:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 16:27'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 18:42:39
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:38:38

[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 (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T10:56:11', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '6e018b83-1d23-4fdb-877f-5afd5df3c5e5'	System	02 Sep 2020 15:58:08
User entered 'None (1)'	System	02 Sep 2020 15:58:08

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T10:56:15', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '6e018b83-1d23-4fdb-877f-5afd5df3c5e5'	System	02 Sep 2020 15:58:08
User entered 'No (N)'	System	02 Sep 2020 15:58:08

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T10:56:17', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '6e018b83-1d23-4fdb-877f-5afd5df3c5e5'	System	02 Sep 2020 15:58:08
User entered 'No (N)'	System	02 Sep 2020 15:58:08

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:38:38

[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 (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T10:56:20', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '6e018b83-1d23-4fdb-877f-5afd5df3c5e5'	System	02 Sep 2020 15:58:08
User entered 'None (1)'	System	02 Sep 2020 15:58:08

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:38:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T10:56:22', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '6e018b83-1d23-4fdb-877f-5afd5df3c5e5'	System	02 Sep 2020 15:58:08
User entered '02 Sep 2020 10:56'	System	02 Sep 2020 15:58:08

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:38:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 17:22'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:38:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 18:42:39
User entered 'Day 2'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:38:38

[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 (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T22:05:17', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '9551b59c-f265-4944-94a1-0a40dfa9b17f'	System	03 Sep 2020 03:05:33
User entered 'None (1)'	System	03 Sep 2020 03:05:33

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T22:05:19', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '9551b59c-f265-4944-94a1-0a40dfa9b17f'	System	03 Sep 2020 03:05:33
User entered 'No (N)'	System	03 Sep 2020 03:05:33

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T22:05:21', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '9551b59c-f265-4944-94a1-0a40dfa9b17f'	System	03 Sep 2020 03:05:33
User entered 'No (N)'	System	03 Sep 2020 03:05:33

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:38:38

[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 (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T22:05:28', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '9551b59c-f265-4944-94a1-0a40dfa9b17f'	System	03 Sep 2020 03:05:33
User entered 'None (1)'	System	03 Sep 2020 03:05:33

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:38:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T22:05:30', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '9551b59c-f265-4944-94a1-0a40dfa9b17f'	System	03 Sep 2020 03:05:33
User entered '02 Sep 2020 22:05'	System	03 Sep 2020 03:05:33

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:38:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:38:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 18:42:39
User entered 'Day 3'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:38:38

[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 (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-03T18:59:13', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '8374f291-347d-4935-afaf-29adde8f76d0'	System	03 Sep 2020 23:59:24
User entered 'None (1)'	System	03 Sep 2020 23:59:24

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:38:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-03T18:59:15', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '8374f291-347d-4935-afaf-29adde8f76d0'	System	03 Sep 2020 23:59:24
User entered 'No (N)'	System	03 Sep 2020 23:59:24

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-03T18:59:18', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '8374f291-347d-4935-afaf-29adde8f76d0'	System	03 Sep 2020 23:59:24
User entered 'No (N)'	System	03 Sep 2020 23:59:24

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:38:38

[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 (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-03T18:59:21', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '8374f291-347d-4935-afaf-29adde8f76d0'	System	03 Sep 2020 23:59:24
User entered 'None (1)'	System	03 Sep 2020 23:59:24

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:38:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-03T18:59:23', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '8374f291-347d-4935-afaf-29adde8f76d0'	System	03 Sep 2020 23:59:24
User entered '03 Sep 2020 18:59'	System	03 Sep 2020 23:59:24

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:38:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:38:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 18:42:39
User entered 'Day 4'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:38:38

[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 (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-04T17:16:39', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '1c0e92f0-a88a-46ea-9a26-56b32d7616a8'	System	04 Sep 2020 22:16:50
User entered 'None (1)'	System	04 Sep 2020 22:16:50

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:38:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-04T17:16:41', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '1c0e92f0-a88a-46ea-9a26-56b32d7616a8'	System	04 Sep 2020 22:16:50
User entered 'No (N)'	System	04 Sep 2020 22:16:50

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-04T17:16:43', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '1c0e92f0-a88a-46ea-9a26-56b32d7616a8'	System	04 Sep 2020 22:16:50
User entered 'No (N)'	System	04 Sep 2020 22:16:50

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:38:38

[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 (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-04T17:16:45', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '1c0e92f0-a88a-46ea-9a26-56b32d7616a8'	System	04 Sep 2020 22:16:50
User entered 'None (1)'	System	04 Sep 2020 22:16:50

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:38:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-04T17:16:47', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '1c0e92f0-a88a-46ea-9a26-56b32d7616a8'	System	04 Sep 2020 22:16:50
User entered '04 Sep 2020 17:16'	System	04 Sep 2020 22:16:50

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:38:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:38:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 18:42:39
User entered 'Day 5'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:38:38

[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 (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-05T17:02:22', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '07f63096-3d6d-49bd-936d-e7e24bbf510e'	System	05 Sep 2020 22:02:36
User entered 'None (1)'	System	05 Sep 2020 22:02:36

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-05T17:02:24', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '07f63096-3d6d-49bd-936d-e7e24bbf510e'	System	05 Sep 2020 22:02:36
User entered 'No (N)'	System	05 Sep 2020 22:02:36

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-05T17:02:25', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '07f63096-3d6d-49bd-936d-e7e24bbf510e'	System	05 Sep 2020 22:02:36
User entered 'No (N)'	System	05 Sep 2020 22:02:36

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:38:38

[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 (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-05T17:02:28', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '07f63096-3d6d-49bd-936d-e7e24bbf510e'	System	05 Sep 2020 22:02:36
User entered 'None (1)'	System	05 Sep 2020 22:02:36

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:38:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-05T17:02:32', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '07f63096-3d6d-49bd-936d-e7e24bbf510e'	System	05 Sep 2020 22:02:36
User entered '05 Sep 2020 17:02'	System	05 Sep 2020 22:02:36

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:38:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:38:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 18:42:39
User entered 'Day 6'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:38:38

[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 (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-06T18:38:42', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'a3974502-22a2-4ba2-b8bf-cc56b2719183'	System	06 Sep 2020 23:38:53
User entered 'None (1)'	System	06 Sep 2020 23:38:53

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-06T18:38:44', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'a3974502-22a2-4ba2-b8bf-cc56b2719183'	System	06 Sep 2020 23:38:53
User entered 'No (N)'	System	06 Sep 2020 23:38:53

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-06T18:38:45', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'a3974502-22a2-4ba2-b8bf-cc56b2719183'	System	06 Sep 2020 23:38:53
User entered 'No (N)'	System	06 Sep 2020 23:38:53

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:38:38

[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 (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-06T18:38:48', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'a3974502-22a2-4ba2-b8bf-cc56b2719183'	System	06 Sep 2020 23:38:53
User entered 'None (1)'	System	06 Sep 2020 23:38:53

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:38:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-06T18:38:50', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'a3974502-22a2-4ba2-b8bf-cc56b2719183'	System	06 Sep 2020 23:38:53
User entered '06 Sep 2020 18:38'	System	06 Sep 2020 23:38:53

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:38:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:38:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 18:42:39
User entered 'Day 7'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:38:38

[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 (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-07T17:19:30', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '8ba94949-7f9b-405f-a439-584e65a24f38'	System	07 Sep 2020 22:19:41
User entered 'None (1)'	System	07 Sep 2020 22:19:41

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:38:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-07T17:19:32', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '8ba94949-7f9b-405f-a439-584e65a24f38'	System	07 Sep 2020 22:19:41
User entered 'No (N)'	System	07 Sep 2020 22:19:41

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-07T17:19:33', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '8ba94949-7f9b-405f-a439-584e65a24f38'	System	07 Sep 2020 22:19:41
User entered 'No (N)'	System	07 Sep 2020 22:19:41

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:38:38

[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 (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-07T17:19:35', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '8ba94949-7f9b-405f-a439-584e65a24f38'	System	07 Sep 2020 22:19:41
User entered 'None (1)'	System	07 Sep 2020 22:19:41

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:38:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-07T17:19:37', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '8ba94949-7f9b-405f-a439-584e65a24f38'	System	07 Sep 2020 22:19:41
User entered '07 Sep 2020 17:19'	System	07 Sep 2020 22:19:41

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:38:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:38:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 18:42:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:38:38

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-01T16:13:05', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '9c78e9e6-952a-4d5f-b273-88ff4cb68890'	System	01 Sep 2020 21:13:34
User entered 'None (0)'	System	01 Sep 2020 21:13:34

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:38:38

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-01T16:13:10', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '9c78e9e6-952a-4d5f-b273-88ff4cb68890'	System	01 Sep 2020 21:13:34
User entered 'None (0)'	System	01 Sep 2020 21:13:34

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:38:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-01T16:13:12', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '9c78e9e6-952a-4d5f-b273-88ff4cb68890'	System	01 Sep 2020 21:13:34
User entered 'None (0)'	System	01 Sep 2020 21:13:34

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:38:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-01T16:13:14', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '9c78e9e6-952a-4d5f-b273-88ff4cb68890'	System	01 Sep 2020 21:13:34
User entered 'None (0)'	System	01 Sep 2020 21:13:34

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:38:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-01T16:13:16', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '9c78e9e6-952a-4d5f-b273-88ff4cb68890'	System	01 Sep 2020 21:13:34
User entered 'None (0)'	System	01 Sep 2020 21:13:34

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:38:38

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-01T16:13:18', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '9c78e9e6-952a-4d5f-b273-88ff4cb68890'	System	01 Sep 2020 21:13:34
User entered 'None (0)'	System	01 Sep 2020 21:13:34

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:38:38

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 (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-01T16:13:27', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '9c78e9e6-952a-4d5f-b273-88ff4cb68890'	System	01 Sep 2020 21:13:34
User entered 'No (N)'	System	01 Sep 2020 21:13:34

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:38:38

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-01T16:13:32', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '9c78e9e6-952a-4d5f-b273-88ff4cb68890'	System	01 Sep 2020 21:13:34
User entered '01 Sep 2020 16:13'	System	01 Sep 2020 21:13:34

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:38:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 13:57'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:38:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 16:27'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 18:42:39
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:38:38

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T10:06:30', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'db128f4f-7c06-4d6a-ad55-ef824504a669'	System	02 Sep 2020 15:06:50
User entered 'No interference with activity (1)'	System	02 Sep 2020 15:06:50

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:38:38

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T10:06:33', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'db128f4f-7c06-4d6a-ad55-ef824504a669'	System	02 Sep 2020 15:06:50
User entered 'None (0)'	System	02 Sep 2020 15:06:50

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:38:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T10:06:35', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'db128f4f-7c06-4d6a-ad55-ef824504a669'	System	02 Sep 2020 15:06:50
User entered 'None (0)'	System	02 Sep 2020 15:06:50

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:38:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T10:06:37', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'db128f4f-7c06-4d6a-ad55-ef824504a669'	System	02 Sep 2020 15:06:50
User entered 'None (0)'	System	02 Sep 2020 15:06:50

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:38:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T10:06:39', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'db128f4f-7c06-4d6a-ad55-ef824504a669'	System	02 Sep 2020 15:06:50
User entered 'None (0)'	System	02 Sep 2020 15:06:50

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:38:38

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T10:06:40', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'db128f4f-7c06-4d6a-ad55-ef824504a669'	System	02 Sep 2020 15:06:50
User entered 'None (0)'	System	02 Sep 2020 15:06:50

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:38:38

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 (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T10:06:43', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'db128f4f-7c06-4d6a-ad55-ef824504a669'	System	02 Sep 2020 15:06:50
User entered 'No (N)'	System	02 Sep 2020 15:06:50

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:38:38

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T10:06:46', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'db128f4f-7c06-4d6a-ad55-ef824504a669'	System	02 Sep 2020 15:06:50
User entered '02 Sep 2020 10:06'	System	02 Sep 2020 15:06:50

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:38:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 17:22'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:38:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 18:42:39
User entered 'Day 2'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:38:38

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T22:04:54', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'eb6edac8-cad2-48fc-a96b-a0561c3a2212'	System	03 Sep 2020 03:05:18
User entered 'No interference with activity (1)'	System	03 Sep 2020 03:05:18

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:38:38

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T22:04:56', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'eb6edac8-cad2-48fc-a96b-a0561c3a2212'	System	03 Sep 2020 03:05:18
User entered 'None (0)'	System	03 Sep 2020 03:05:18

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:38:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T22:04:58', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'eb6edac8-cad2-48fc-a96b-a0561c3a2212'	System	03 Sep 2020 03:05:18
User entered 'None (0)'	System	03 Sep 2020 03:05:18

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:38:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T22:04:59', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'eb6edac8-cad2-48fc-a96b-a0561c3a2212'	System	03 Sep 2020 03:05:18
User entered 'None (0)'	System	03 Sep 2020 03:05:18

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:38:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T22:05:01', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'eb6edac8-cad2-48fc-a96b-a0561c3a2212'	System	03 Sep 2020 03:05:18
User entered 'None (0)'	System	03 Sep 2020 03:05:18

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:38:38

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T22:05:03', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'eb6edac8-cad2-48fc-a96b-a0561c3a2212'	System	03 Sep 2020 03:05:18
User entered 'None (0)'	System	03 Sep 2020 03:05:18

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:38:38

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 (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T22:05:10', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'eb6edac8-cad2-48fc-a96b-a0561c3a2212'	System	03 Sep 2020 03:05:18
User entered 'No (N)'	System	03 Sep 2020 03:05:18

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:38:38

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-02T22:05:13', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'eb6edac8-cad2-48fc-a96b-a0561c3a2212'	System	03 Sep 2020 03:05:18
User entered '02 Sep 2020 22:05'	System	03 Sep 2020 03:05:18

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:38:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:38:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:38:38

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 18:42:39
User entered 'Day 3'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:38:38

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-03T18:58:55', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '7ca7c148-7165-469e-83f0-e49ff5f52b2f'	System	03 Sep 2020 23:59:13
User entered 'None (0)'	System	03 Sep 2020 23:59:13

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:38:38

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-03T18:58:56', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '7ca7c148-7165-469e-83f0-e49ff5f52b2f' User entered 'None (0)'	System	03 Sep 2020 23:59:13
	System	03 Sep 2020 23:59:13

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:38:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-03T18:58:58', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '7ca7c148-7165-469e-83f0-e49ff5f52b2f'	System	03 Sep 2020 23:59:13
User entered 'None (0)'	System	03 Sep 2020 23:59:13

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:38:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-03T18:59:00', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '7ca7c148-7165-469e-83f0-e49ff5f52b2f' User entered 'None (0)'	System	03 Sep 2020 23:59:13

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:38:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-03T18:59:02', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '7ca7c148-7165-469e-83f0-e49ff5f52b2f'	System	03 Sep 2020 23:59:13
User entered 'None (0)'	System	03 Sep 2020 23:59:13

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:38:38

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-03T18:59:03', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '7ca7c148-7165-469e-83f0-e49ff5f52b2f' User entered 'None (0)'	System	03 Sep 2020 23:59:13
	System	03 Sep 2020 23:59:13

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:38:38

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 (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-03T18:59:06', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '7ca7c148-7165-469e-83f0-e49ff5f52b2f' User entered 'No (N)'	System	03 Sep 2020 23:59:13

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:38:38

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-03T18:59:09', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '7ca7c148-7165-469e-83f0-e49ff5f52b2f' User entered '03 Sep 2020 18:59'	System	03 Sep 2020 23:59:13
	System	03 Sep 2020 23:59:13

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:38:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:38:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 18:42:39
User entered 'Day 4'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:38:38

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-04T17:15:41', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'eb037b9c-c9e5-440c-84f0-e95b008bb679'	System	04 Sep 2020 22:16:03
User entered 'No interference with activity (1)'	System	04 Sep 2020 22:16:03

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:38:38

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-04T17:15:48', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'eb037b9c-c9e5-440c-84f0-e95b008bb679'	System	04 Sep 2020 22:16:03
User entered 'None (0)'	System	04 Sep 2020 22:16:03

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:38:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-04T17:15:50', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'eb037b9c-c9e5-440c-84f0-e95b008bb679'	System	04 Sep 2020 22:16:03
User entered 'None (0)'	System	04 Sep 2020 22:16:03

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:38:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-04T17:15:52', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'eb037b9c-c9e5-440c-84f0-e95b008bb679'	System	04 Sep 2020 22:16:03
User entered 'None (0)'	System	04 Sep 2020 22:16:03

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:38:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-04T17:15:54', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'eb037b9c-c9e5-440c-84f0-e95b008bb679'	System	04 Sep 2020 22:16:03
User entered 'None (0)'	System	04 Sep 2020 22:16:03

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:38:38

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-04T17:15:55', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'eb037b9c-c9e5-440c-84f0-e95b008bb679'	System	04 Sep 2020 22:16:03
User entered 'None (0)'	System	04 Sep 2020 22:16:03

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:38:38

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 (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-04T17:15:57', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'eb037b9c-c9e5-440c-84f0-e95b008bb679'	System	04 Sep 2020 22:16:03
User entered 'No (N)'	System	04 Sep 2020 22:16:03

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:38:38

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-04T17:15:59', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'eb037b9c-c9e5-440c-84f0-e95b008bb679'	System	04 Sep 2020 22:16:03
User entered '04 Sep 2020 17:15'	System	04 Sep 2020 22:16:03

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:38:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:38:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:38:38

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 18:42:39
User entered 'Day 5'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:38:38

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-05T17:02:05', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '444b819f-8ddc-4099-8e65-e21eb6e51766'	System	05 Sep 2020 22:02:19
User entered 'None (0)'	System	05 Sep 2020 22:02:19

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:38:38

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-05T17:02:07', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '444b819f-8ddc-4099-8e65-e21eb6e51766'	System	05 Sep 2020 22:02:19
User entered 'None (0)'	System	05 Sep 2020 22:02:19

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:38:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-05T17:02:09', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '444b819f-8ddc-4099-8e65-e21eb6e51766'	System	05 Sep 2020 22:02:19
User entered 'None (0)'	System	05 Sep 2020 22:02:19

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:38:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-05T17:02:10', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '444b819f-8ddc-4099-8e65-e21eb6e51766'	System	05 Sep 2020 22:02:19
User entered 'None (0)'	System	05 Sep 2020 22:02:19

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:38:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-05T17:02:11', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '444b819f-8ddc-4099-8e65-e21eb6e51766'	System	05 Sep 2020 22:02:19
User entered 'None (0)'	System	05 Sep 2020 22:02:19

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:38:38

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-05T17:02:12', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '444b819f-8ddc-4099-8e65-e21eb6e51766'	System	05 Sep 2020 22:02:19
User entered 'None (0)'	System	05 Sep 2020 22:02:19

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:38:38

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 (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-05T17:02:14', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '444b819f-8ddc-4099-8e65-e21eb6e51766'	System	05 Sep 2020 22:02:19
User entered 'No (N)'	System	05 Sep 2020 22:02:19

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:38:38

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-05T17:02:17', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '444b819f-8ddc-4099-8e65-e21eb6e51766'	System	05 Sep 2020 22:02:19
User entered '05 Sep 2020 17:02'	System	05 Sep 2020 22:02:19

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:38:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:38:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:38:38

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 18:42:39
User entered 'Day 6'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:38:38

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-06T18:38:29', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '9ee00e7e-0f9b-4601-a86f-6b3d74ae11b0'	System	06 Sep 2020 23:38:41
User entered 'None (0)'	System	06 Sep 2020 23:38:41

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:38:38

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-06T18:38:30', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '9ee00e7e-0f9b-4601-a86f-6b3d74ae11b0'	System	06 Sep 2020 23:38:41
User entered 'None (0)'	System	06 Sep 2020 23:38:41

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:38:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-06T18:38:31', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '9ee00e7e-0f9b-4601-a86f-6b3d74ae11b0'	System	06 Sep 2020 23:38:41
User entered 'None (0)'	System	06 Sep 2020 23:38:41

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:38:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-06T18:38:32', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '9ee00e7e-0f9b-4601-a86f-6b3d74ae11b0'	System	06 Sep 2020 23:38:41
User entered 'None (0)'	System	06 Sep 2020 23:38:41

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:38:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-06T18:38:34', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '9ee00e7e-0f9b-4601-a86f-6b3d74ae11b0'	System	06 Sep 2020 23:38:41
User entered 'None (0)'	System	06 Sep 2020 23:38:41

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:38:38

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-06T18:38:35', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '9ee00e7e-0f9b-4601-a86f-6b3d74ae11b0'	System	06 Sep 2020 23:38:41
User entered 'None (0)'	System	06 Sep 2020 23:38:41

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:38:38

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 (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-06T18:38:37', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '9ee00e7e-0f9b-4601-a86f-6b3d74ae11b0'	System	06 Sep 2020 23:38:41
User entered 'No (N)'	System	06 Sep 2020 23:38:41

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:38:38

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-06T18:38:39', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '9ee00e7e-0f9b-4601-a86f-6b3d74ae11b0'	System	06 Sep 2020 23:38:41
User entered '06 Sep 2020 18:38'	System	06 Sep 2020 23:38:41

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:38:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:38:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 18:42:39
User entered 'Day 7'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:38:38

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-07T17:19:10', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'cc5a30f0-c13e-4d41-8fa6-a7f2225c066a'	System	07 Sep 2020 22:19:28
User entered 'No interference with activity (1)'	System	07 Sep 2020 22:19:28

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:38:38

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-07T17:19:12', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'cc5a30f0-c13e-4d41-8fa6-a7f2225c066a' User entered 'None (0)'	System	07 Sep 2020 22:19:28

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:38:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-07T17:19:15', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'cc5a30f0-c13e-4d41-8fa6-a7f2225c066a' User entered 'None (0)'	System	07 Sep 2020 22:19:28

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:38:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-07T17:19:16', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'cc5a30f0-c13e-4d41-8fa6-a7f2225c066a' User entered 'None (0)'	System	07 Sep 2020 22:19:28

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:38:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-07T17:19:18', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'cc5a30f0-c13e-4d41-8fa6-a7f2225c066a' User entered 'None (0)'	System	07 Sep 2020 22:19:28

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:38:38

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-07T17:19:19', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'cc5a30f0-c13e-4d41-8fa6-a7f2225c066a' User entered 'None (0)'	System	07 Sep 2020 22:19:28

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:38:38

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 (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-07T17:19:24', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'cc5a30f0-c13e-4d41-8fa6-a7f2225c066a'	System	07 Sep 2020 22:19:28
User entered 'No (N)'	System	07 Sep 2020 22:19:28

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:38:38

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-07T17:19:26', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'cc5a30f0-c13e-4d41-8fa6-a7f2225c066a' User entered '07 Sep 2020 17:19'	System	07 Sep 2020 22:19:28
	System	07 Sep 2020 22:19:28

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:38:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:38:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 18:42:39

US3552273

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Sep 2020 22:19:28
User entered 'Day 8'	System	07 Sep 2020 22:19:28

US3552273

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 09:38:38

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-08T15:50:03', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '1dcfb5fb-333e-48e8-96e6-318a37349d7d'	System	08 Sep 2020 20:50:09
User entered 'None (0)'	System	08 Sep 2020 20:50:09

US3552273

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 09:38:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-08T15:50:06', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '1dcfb5fb-333e-48e8-96e6-318a37349d7d'	System	08 Sep 2020 20:50:09
User entered '08 Sep 2020 15:50'	System	08 Sep 2020 20:50:09

US3552273

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 09:38:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	07 Sep 2020 22:19:28

US3552273

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 09:38:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	07 Sep 2020 22:19:28

US3552273

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Sep 2020 22:19:28
User entered 'Day 8'	System	07 Sep 2020 22:19:28

US3552273

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:38:38

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 (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-08T15:50:11', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '91c5725a-cd13-4b9f-9605-eb3bb167d4d7'	System	08 Sep 2020 20:50:15
User entered 'No (N)'	System	08 Sep 2020 20:50:15

US3552273

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:38:38

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-09-08T15:50:14', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '91c5725a-cd13-4b9f-9605-eb3bb167d4d7'	System	08 Sep 2020 20:50:15
User entered '08 Sep 2020 15:50'	System	08 Sep 2020 20:50:15

US3552273

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:38:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	07 Sep 2020 22:19:28

US3552273

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:38:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	07 Sep 2020 22:19:28

US3552273

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	08 Sep 2020 17:31:32

US3552273

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:38

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020' reason for change: Data Entry Error	Stanley Dublin (b) (4)	10 Nov 2020 20:12:51
User entered '8 Sep 2020'	Stanley Dublin (b) (4)	08 Sep 2020 17:31:32

US3552273

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4)	08 Sep 2020 17:31:32

US3552273

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Stanley Doublin (b) (4) (b) (4)	08 Sep 2020 17:31:32

US3552273

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	15 Sep 2020 17:44:32

US3552273

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 17:44:32

US3552273

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	15 Sep 2020 17:44:40

US3552273

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered '15 Sep 2020'	Stanley Dublin (b) (4) (b) (4)	15 Sep 2020 17:44:40

US3552273

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4)	15 Sep 2020 17:44:40

US3552273

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	15 Sep 2020 17:44:40

US3552273

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 14:44:56

US3552273

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 14:44:56

US3552273

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 14:45:07

US3552273

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:38

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020'	Stanley Dublin (b) (4) (b) (4)	23 Sep 2020 14:45:07

US3552273

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4)	23 Sep 2020 14:45:07

US3552273

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Stanley Doublin (b) (4) (b) (4)	23 Sep 2020 14:45:07

US3552273

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 16:29:12

US3552273

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 16:29:12

US3552273

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:38:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 16:29:24

US3552273

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered '28 Sep 2020'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 16:29:24

US3552273

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 16:29:24

US3552273

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:38:38

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	28 Sep 2020 16:29:24

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:38

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 16:31:02

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 16:31:02

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered '28 Sep 2020'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 16:31:02

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered '09:02'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 16:31:02

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered '28 Sep 2020 09:02'	System	28 Sep 2020 16:31:02

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:38

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.1' F	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 16:31:02

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:38

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 16:31:02

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:38

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 16:31:02

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	30 Sep 2020 04:20:40
Query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'CS, AE ongoing' (Site from System).	Heather Douds (b) (4)	28 Sep 2020 20:12:57
User opened query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	28 Sep 2020 16:31:02
User entered '140'	Stanley Dublin (b) (4)	28 Sep 2020 16:31:02

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:38

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	28 Sep 2020 16:31:02

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered '18'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 16:31:02

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	28 Sep 2020 16:31:02

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered '162'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 16:31:02

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Sep 2020 16:31:02

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered '98'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 16:31:02

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:38:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Sep 2020 16:31:02

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:38

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 16:36:21

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 16:36:21

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 16:36:21

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 16:36:21

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 16:36:21

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:38

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 16:36:21

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:38

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 16:36:21

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:38

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 16:36:21

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 16:36:21

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:38

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 16:36:21

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 16:36:21

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 16:36:21

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 16:36:21

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 16:36:21

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 16:36:21

US3552273

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:38:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 16:36:21

US3552273

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:38:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 16:34:51

US3552273

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:38:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '28 Sep 2020'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 16:34:51

US3552273

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:38:38

[Was study treatment given?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Please complete the end of study dosing discontinuation page.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 10:39:09
Query 'Per CDM: Please complete the end of study dosing discontinuation page.' answered with 'updated' (Site from DM).	Heather Douds (b) (4) (b) (4)	06 Oct 2020 14:05:22
User opened query 'Per CDM: Please complete the end of study dosing discontinuation page.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 08:58:20
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	28 Sep 2020 16:35:51

US3552273

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:38:38

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered 'Physician Decision (PHYSICIAN DECISION)'	Stanley Dublin (b) (4)	28 Sep 2020 16:35:51

US3552273

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered 'Anxiety' reason for change: Data Entry Error	Heather Douds (b) (4)	28 Sep 2020 20:19:38
User entered 'BP and HP elevated due to anxiety per Dr. Frey'	Stanley Dublin (b) (4)	28 Sep 2020 16:35:51

US3552273

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:38:38

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 16:35:51

US3552273

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:38:38

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 16:35:51

US3552273

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:38:38

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 16:35:51

US3552273

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:38:38

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 16:35:51

US3552273

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:38:38

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 16:35:51

US3552273

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:38:38

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 16:35:51

US3552273

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:38:38

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 16:35:51

US3552273

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:38:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 16:36:13

US3552273

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:38:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Sep 2020'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 16:36:13

US3552273

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:38:38

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '09:30'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 16:36:13

US3552273

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:38:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 09:30'	System	28 Sep 2020 16:36:13

US3552273

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered '28 Sep 2020'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 16:36:36

US3552273

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:38:38

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Stanley Dublin (b) (4)	28 Sep 2020 16:36:36

US3552273

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:38:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 16:36:36

US3552273

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:38:38

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered '09:32'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 16:36:36

US3552273

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:38:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 09:32'	System	28 Sep 2020 16:36:36

US3552273

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:38:38

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Stanley Dublin (b) (4)	28 Sep 2020 16:36:36

US3552273

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:38:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 16:36:36

US3552273

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:38:38

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	28 Sep 2020 16:36:36

US3552273

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:38:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 16:36:36

US3552273

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	05 Oct 2020 18:30:39

US3552273

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 18:30:39

US3552273

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	05 Oct 2020 18:30:47

US3552273

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:38

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020' reason for change: Data Entry Error	Stanley Dublin (b) (4)	10 Nov 2020 20:13:09
User entered '5 Oct 2020'	Stanley Dublin (b) (4)	05 Oct 2020 18:30:47

US3552273

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4)	05 Oct 2020 18:30:47

US3552273

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Stanley Doublin (b) (4) (b) (4)	05 Oct 2020 18:30:47

US3552273

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 18:53:55

US3552273

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 18:53:55

US3552273

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	12 Oct 2020 18:54:04

US3552273

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:38

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020'	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 18:54:04

US3552273

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4)	12 Oct 2020 18:54:04

US3552273

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	12 Oct 2020 18:54:04

US3552273

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 17:49:29

US3552273

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 17:49:29

US3552273

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 17:49:37

US3552273

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:38

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 17:49:37

US3552273

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4)	19 Oct 2020 17:49:37

US3552273

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 17:49:37

US3552273

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	04 Nov 2020 13:02:54

US3552273

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Nov 2020 13:02:54

US3552273

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:38:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	04 Nov 2020 13:03:03

US3552273

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered '03 Nov 2020' reason for change: Data Entry Error	Stanley Dublin (b) (4)	10 Nov 2020 20:13:17
User entered '3 Nov 2020'	Stanley Dublin (b) (4)	04 Nov 2020 13:03:03

US3552273

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Stanley Doublin (b) (4) (b) (4)	04 Nov 2020 13:03:03

US3552273

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:38:38

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	04 Nov 2020 13:03:03

US3552273

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	04 Nov 2020 13:03:32

US3552273

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered '03 Nov 2020' reason for change: Data Entry Error	Stanley Dublin (b) (4)	10 Nov 2020 20:13:24
User entered '3 Nov 2020'	Stanley Dublin (b) (4)	04 Nov 2020 13:03:32

US3552273

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered '14:05'	Stanley Dublin (b) (4) (b) (4)	04 Nov 2020 13:03:32

US3552273

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered '03 Nov 2020 14:05'	System	10 Nov 2020 20:13:24
User entered '3 Nov 2020 14:05'	System	04 Nov 2020 13:03:32

US3552273

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:38

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.5' F	Stanley Dublin (b) (4) (b) (4)	04 Nov 2020 13:03:32

US3552273

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:38

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Stanley Dublin (b) (4) (b) (4)	04 Nov 2020 13:03:32

US3552273

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:38

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	04 Nov 2020 13:03:32

US3552273

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '99'	Stanley Dublin (b) (4) (b) (4)	04 Nov 2020 13:03:32

US3552273

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:38

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	04 Nov 2020 13:03:32

US3552273

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered '16'	Stanley Doublin (b) (4) (b) (4)	04 Nov 2020 13:03:32

US3552273

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	04 Nov 2020 13:03:32

US3552273

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered '122'	Stanley Dublin (b) (4) (b) (4)	04 Nov 2020 13:03:32

US3552273

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	04 Nov 2020 13:03:32

US3552273

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered '80'	Stanley Doublin (b) (4) (b) (4)	04 Nov 2020 13:03:32

US3552273

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:38:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	04 Nov 2020 13:03:32

US3552273

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:38:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	04 Nov 2020 13:03:40

US3552273

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:38:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	04 Nov 2020 13:03:40

US3552273

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:38:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	04 Nov 2020 13:03:51

US3552273

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered '03 Nov 2020' reason for change: Data Entry Error	Stanley Dublin (b) (4)	10 Nov 2020 20:13:33
User entered '3 Nov 2020'	Stanley Dublin (b) (4)	04 Nov 2020 13:03:51

US3552273

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:38:38

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '14:12'	Stanley Doublin (b) (4) (b) (4)	04 Nov 2020 13:03:51

US3552273

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:38:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '03 Nov 2020 14:12'	System	10 Nov 2020 20:13:33
User entered '3 Nov 2020 14:12'	System	04 Nov 2020 13:03:51

US3552273

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	24 Nov 2020 13:39:51

US3552273

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:38:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 13:39:51

US3552273

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 18:42:39
User entered 'Day 64'	System	01 Sep 2020 18:42:39

US3552273

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[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 (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-11-01T08:14:36', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'e6a1c880-5e3b-4a3b-9d3f-6c7eb7bdabea' User entered 'No (N)'	System	01 Nov 2020 16:14:47

US3552273

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

Have you been exposed to someone with 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 (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-11-01T08:14:39', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'e6a1c880-5e3b-4a3b-9d3f-6c7eb7bdabea' User entered 'No (N)'	System	01 Nov 2020 16:14:47

US3552273

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (76869885-4350-4BE1-82C5-4A4FDA453170)', Time: '2020-11-01T08:14:43', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'e6a1c880-5e3b-4a3b-9d3f-6c7eb7bdabea' User entered '01 Nov 2020 08:14:43'	System	01 Nov 2020 16:14:47
	System	01 Nov 2020 16:14:47

US3552273

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 18:42:39
User entered '01 Nov 2020 00:01'	System	01 Sep 2020 18:42:39

US3552273

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 18:42:39
User entered '05 Nov 2020 23:59'	System	01 Sep 2020 18:42:39

US3552273

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 18:42:39
User entered 'Day 71'	System	01 Sep 2020 18:42:39

US3552273

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2020-11-12T11:40:27', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '18819f54-e2ad-44f0-a8f7-c0933f73fe35'	System	12 Nov 2020 17:40:40
User entered 'No (N)'	System	12 Nov 2020 17:40:40

US3552273

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

Have you been exposed to someone with 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 (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2020-11-12T11:40:33', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '18819f54-e2ad-44f0-a8f7-c0933f73fe35'	System	12 Nov 2020 17:40:40
User entered 'No (N)'	System	12 Nov 2020 17:40:40

US3552273

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2020-11-12T11:40:37', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '18819f54-e2ad-44f0-a8f7-c0933f73fe35'	System	12 Nov 2020 17:40:40
User entered '12 Nov 2020 11:40:37'	System	12 Nov 2020 17:40:40

US3552273

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 18:42:39
User entered '08 Nov 2020 00:01'	System	01 Sep 2020 18:42:39

US3552273

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 18:42:39
User entered '12 Nov 2020 23:59'	System	01 Sep 2020 18:42:39

US3552273

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 18:42:39
User entered 'Day 78'	System	01 Sep 2020 18:42:39

US3552273

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2020-11-15T07:05:26', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '3d72322e-db56-4ef6-8880-d03faff13eeb' User entered 'No (N)'	System	15 Nov 2020 13:05:41

US3552273

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

Have you been exposed to someone with 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 (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2020-11-15T07:05:33', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '3d72322e-db56-4ef6-8880-d03faff13eeb'	System	15 Nov 2020 13:05:41
User entered 'No (N)'	System	15 Nov 2020 13:05:41

US3552273

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2020-11-15T07:05:38', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: '3d72322e-db56-4ef6-8880-d03faff13eeb' User entered '15 Nov 2020 07:05:38'	System	15 Nov 2020 13:05:41
	System	15 Nov 2020 13:05:41

US3552273

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 18:42:39
User entered '15 Nov 2020 00:01'	System	01 Sep 2020 18:42:39

US3552273

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 18:42:39
User entered '19 Nov 2020 23:59'	System	01 Sep 2020 18:42:39

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '29 Oct 2020 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '02 Nov 2020 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '05 Nov 2020 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '09 Nov 2020 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '12 Nov 2020 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '16 Nov 2020 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

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 (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2020-11-22T14:02:02', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'f97fc241-6189-4432-a1f7-b56e124b641c'	System	22 Nov 2020 20:02:22
User entered 'No (N)'	System	22 Nov 2020 20:02:22

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

Have you been exposed to someone with 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 (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2020-11-22T14:02:06', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'f97fc241-6189-4432-a1f7-b56e124b641c'	System	22 Nov 2020 20:02:22
User entered 'No (N)'	System	22 Nov 2020 20:02:22

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74EF7EA5-4BFA-484A-BC19-A8928CBAC552)', Time: '2020-11-22T14:02:18', User OID: 'PatientReportedOutcome (US3552273)', ODM File OID: 'f97fc241-6189-4432-a1f7-b56e124b641c' User entered '22 Nov 2020 14:02:18'	System	22 Nov 2020 20:02:22
	System	22 Nov 2020 20:02:22

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 21:54:28

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 21:54:28

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '20 Oct 2022 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '24 Oct 2022 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '27 Oct 2022 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '31 Oct 2022 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '03 Nov 2022 00:01'	System	19 Nov 2020 21:54:28

US3552273

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:38:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:54:28
Amendment Manager: User entered '07 Nov 2022 23:59'	System	19 Nov 2020 21:54:28

US3552273

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	24 Nov 2020 13:40:23

US3552273

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:38

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '23 Nov 2020'	Stanley Dublin (b) (4) (b) (4)	24 Nov 2020 13:40:23

US3552273

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Stanley Dublin (b) (4) (b) (4)	24 Nov 2020 13:40:23

US3552273

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:38:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	24 Nov 2020 13:40:23

US3552273

Folder: Covid-19 Assessment 03 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:38:38

[Date of Contact](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	08 Sep 2020 06:21:19
Query 'Data is required. Please complete.' answered with 'Entered in error' (Site from System).	Heather Douds (b) (4)	04 Sep 2020 13:43:55
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty; reason for change Data Entry Error	System	04 Sep 2020 13:43:28
User entered '3 Sep 2020'	Heather Douds (b) (4)	04 Sep 2020 13:43:28
	(b) (4)	
	Heather Douds (b) (4)	04 Sep 2020 13:42:03
	(b) (4)	

US3552273

Folder: Covid-19 Assessment 03 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:38:38

[Time of Contact](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	08 Sep 2020 06:21:21
Query 'Data is required. Please complete.' answered with 'Entered in error' (Site from System).	Heather Douds (b) (4)	04 Sep 2020 13:43:54
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty; reason for change Data Entry Error	System	04 Sep 2020 13:43:28
User entered '14:00'	Heather Douds (b) (4)	04 Sep 2020 13:43:28
	(b) (4)	
	Heather Douds (b) (4)	04 Sep 2020 13:42:03
	(b) (4)	

US3552273

Folder: Covid-19 Assessment 03 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:38:38

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 13:43:28
User entered '3 Sep 2020 14:00'	System	04 Sep 2020 13:42:03

US3552273

Folder: Covid-19 Assessment 03 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:38:38

[Type of Contact](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	08 Sep 2020 06:21:25
Query 'Data is required. Please complete.' answered with 'Entered in error' (Site from System).	Heather Douds (b) (4)	04 Sep 2020 13:43:53
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty; reason for change Data Entry Error	System	04 Sep 2020 13:43:28
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	Heather Douds (b) (4)	04 Sep 2020 13:42:03
	(b) (4)	

US3552273

Folder: Covid-19 Assessment 03 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:38:38

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	08 Sep 2020 06:21:27
Query 'Data is required. Please complete.' answered with 'Entered in error' (Site from System).	Heather Douds (b) (4)	04 Sep 2020 13:43:51
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty; reason for change Data Entry Error	System	04 Sep 2020 13:43:28
User entered 'Yes (Y)'	Heather Douds (b) (4)	04 Sep 2020 13:43:28
	(b) (4)	
	Heather Douds (b) (4)	04 Sep 2020 13:42:03
	(b) (4)	

US3552273

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:38:38

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 14:05:06

US3552273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:38

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: RQ: Response noted, however, the term was reverted to "HYPERTENSTION" only. Please review and verify if this is a worsening of the Med History condition. If yes, please add "WORSENING" in the AE term. If not, kindly remove this entry. Otherwise, clarify in query response.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 11:26:34
User coded data point as SOC: Vascular disorders, HLGt: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension worsened - version MedDRA\23.0.	Coder Import (b) (4)	23 Oct 2020 15:00:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	23 Oct 2020 15:00:36
Data point term sent to Coder	System	23 Oct 2020 14:59:39
Query 'Per DM CLR: RQ: Response noted, however, the term was reverted to "HYPERTENSTION" only. Please review and verify if this is a worsening of the Med History condition. If yes, please add "WORSENING" in the AE term. If not, kindly remove this entry. Otherwise, clarify in query response.' answered with 'Updated per query request' (Site from DM).	Cassandra Zehenny (b) (4)	23 Oct 2020 14:59:20
Coding entries removed.	(b) (4)	23 Oct 2020 14:59:12
User entered 'Worsening HYPERTENSION' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	23 Oct 2020 14:59:12
User opened query 'Per DM CLR: RQ: Response noted, however, the term was reverted to "HYPERTENSTION" only. Please review and verify if this is a worsening of the Med History condition. If yes, please add "WORSENING" in the AE term. If not, kindly remove this entry. Otherwise, clarify in query response.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 01:59:29
User closed query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH conditon. If yes, update the event term to reflect 'worsening' and update any corresponding CMs, as applicable. Otherwise, provide clarifications. ' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 08:34:19

US3552273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:38

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 18:43:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 18:43:53
Data point term sent to Coder	System	30 Sep 2020 18:42:51
Coding entries removed.	Heather Douds (b) (4) (b) (4)	30 Sep 2020 18:42:34
User entered 'HYPERTENSION' reason for change: Per Query Resolution	Heather Douds (b) (4) (b) (4)	30 Sep 2020 18:42:34
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension worsened - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 17:55:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 17:55:55
Data point term sent to Coder	System	30 Sep 2020 17:55:08
Query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH conditon. If yes, update the event term to reflect 'worsening' and update any corresponding CMs, as applicable. Otherwise, provide clarifications.	(b) (4), (b) (6)	30 Sep 2020 17:54:31
' answered with 'Updated to worsening hypertension' (Site from DM).		
Coding entries removed.	(b) (4), (b) (6)	30 Sep 2020 17:54:16
User entered 'Worsening HYPERTENSION' reason for change: Per Query Resolution	(b) (4), (b) (6)	30 Sep 2020 17:54:16
User opened query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH conditon. If yes, update the event term to reflect 'worsening' and update any corresponding CMs, as applicable. Otherwise, provide clarifications.	(b) (4), (b) (6)	30 Sep 2020 01:52:05
' (Site from DM).		
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 14:14:27

US3552273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:38

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	02 Sep 2020 14:14:27
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	02 Sep 2020 14:12:57
User entered 'hypertension'	Stanley Doublin (b) (4)	02 Sep 2020 14:11:57
	(b) (4)	

US3552273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 14:11:57

US3552273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 14:11:57

US3552273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 14:11:57

US3552273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered '01 Sep 2020' reason for change: Data Entry Error	Stanley Dublin (b) (4)	10 Nov 2020 20:14:04
User entered '1 Sep 2020'	Stanley Dublin (b) (4)	02 Sep 2020 14:11:57

US3552273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:38

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	02 Sep 2020 14:15:22
User entered '14:07' reason for change: Data Entry Error	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 14:15:22
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Sep 2020 14:11:57
User entered empty.	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 14:11:57

US3552273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 14:07'	System	10 Nov 2020 20:14:04
User entered '1 Sep 2020 14:07'	System	02 Sep 2020 14:15:22
User entered empty.	System	02 Sep 2020 14:11:57

US3552273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:38

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: New Information	Heather Douds (b) (4) (b) (4)	28 Sep 2020 20:13:42
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	02 Sep 2020 20:13:28
User entered 'No (N)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	02 Sep 2020 20:13:28
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	02 Sep 2020 20:13:11
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 14:11:57

US3552273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:38

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty; reason for change New Information	Heather Douds (b) (4)	28 Sep 2020 20:13:42
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	02 Sep 2020 20:13:11
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	02 Sep 2020 20:13:11
User entered '01 Sep 2020' reason for change: Data Entry Error	Heather Douds (b) (4)	02 Sep 2020 20:13:11
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	02 Sep 2020 20:12:51
User entered empty.	Stanley Dublin (b) (4)	02 Sep 2020 14:11:57

US3552273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:38

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User closed query 'Ongoing is Yes, but End Time is provided. Please correct.' (Site from System).	System	28 Sep 2020 20:13:50
User entered empty; reason for change Data Entry Error	Heather Douds (b) (4) (b) (4)	28 Sep 2020 20:13:50
User opened query 'Ongoing is Yes, but End Time is provided. Please correct.' (Site from System).	System	28 Sep 2020 20:13:42
User closed query 'Data is required. Please provide.' (Site from System).	System	02 Sep 2020 20:13:45
User entered '16:36' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	02 Sep 2020 20:13:45
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Sep 2020 20:13:28
User entered empty.	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 14:11:57

US3552273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 20:13:42
User entered '01 Sep 2020 16:36'	System	02 Sep 2020 20:13:45
User entered empty.	System	02 Sep 2020 14:11:57

US3552273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:38

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	02 Sep 2020 20:12:51
User entered 'Grade 1/Mild (Grade 1/Mild)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 14:11:57

US3552273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 14:11:57

US3552273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:38

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 14:11:57

US3552273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:38

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 14:11:57

US3552273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 14:11:57

US3552273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:38

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 14:11:57

US3552273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:38

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 14:11:57

US3552273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 14:11:57

US3552273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 14:11:57

US3552273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 14:11:57

US3552273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 14:11:57

US3552273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:38

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 14:11:57

US3552273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 14:11:57

US3552273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 14:11:57

US3552273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:38

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	20 Nov 2020 09:48:11
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'will update' (Site from System).	Cassandra Zehenny (b) (4)	19 Nov 2020 16:34:04
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	19 Nov 2020 16:33:50
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	19 Nov 2020 16:33:50
User entered 'None (NONE)'	Stanley Doublin (b) (4)	02 Sep 2020 14:11:57

US3552273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:38

[None](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 14:11:57

US3552273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 14:11:57

US3552273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 14:11:57

US3552273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:38

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: New Information	Heather Douds (b) (4) (b) (4)	28 Sep 2020 20:13:42
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	02 Sep 2020 20:12:51
User entered 'Unknown (UNKNOWN)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:11:57

US3552273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:38

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 14:11:57

US3552273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:38

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 14:11:57

US3552273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:38

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Sep 2020 14:11:57

US3552273

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:38:38

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 14:11:57

US3552273

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:38

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please specify the type of TACHYCARDIA (e.g., SINUS TACHYCARDIA, VENTRICULAR TACHYCARDIA, etc). 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)	02 Oct 2020 08:33:42
Query 'Per DM CLR: Please specify the type of TACHYCARDIA (e.g., SINUS TACHYCARDIA, VENTRICULAR TACHYCARDIA, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.'	Heather Douds (b) (4)	30 Sep 2020 18:42:44
answered with 'unknown' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Please specify the type of TACHYCARDIA (e.g., SINUS TACHYCARDIA, VENTRICULAR TACHYCARDIA, etc). 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)	30 Sep 2020 01:52:27
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Rate and rhythm disorders NEC, PT: Tachycardia, LLT: Tachycardia - version MedDRA\23.0.	Coder Import (b) (4)	02 Sep 2020 14:14:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	02 Sep 2020 14:14:43
Data point term sent to Coder	System	02 Sep 2020 14:13:59
User entered 'tachycardia'	Stanley Dublin (b) (4)	02 Sep 2020 14:13:19
	(b) (4)	

US3552273

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 14:13:19

US3552273

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 14:13:19

US3552273

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 14:13:19

US3552273

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered '01 Sep 2020' reason for change: Data Entry Error	Stanley Dublin (b) (4)	10 Nov 2020 20:14:22
User entered '1 Sep 2020'	Stanley Dublin (b) (4)	02 Sep 2020 14:13:19

US3552273

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:38

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	02 Sep 2020 14:15:12
User entered '14:07' reason for change: Data Entry Error	Stanley Dublin (b) (4)	02 Sep 2020 14:15:12
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Sep 2020 14:13:19
User entered empty.	Stanley Dublin (b) (4)	02 Sep 2020 14:13:19

US3552273

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 14:07'	System	10 Nov 2020 20:14:22
User entered '1 Sep 2020 14:07'	System	02 Sep 2020 14:15:12
User entered empty.	System	02 Sep 2020 14:13:19

US3552273

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:38

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Heather Douds (b) (4)	28 Sep 2020 20:14:48
User entered 'No (N)' reason for change: Data Entry Error	Heather Douds (b) (4)	02 Sep 2020 20:15:16
User entered 'Yes (Y)'	Stanley Dublin (b) (4)	02 Sep 2020 14:13:19

US3552273

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:38

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty; reason for change New Information	Heather Douds (b) (4)	28 Sep 2020 20:14:48
User entered '01 Sep 2020' reason for change: Data Entry Error	Heather Douds (b) (4)	02 Sep 2020 20:15:16
User entered empty.	Stanley Dublin (b) (4)	02 Sep 2020 14:13:19

US3552273

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:38

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty; reason for change New Information	Heather Douds (b) (4)	28 Sep 2020 20:14:48
User entered '16:36' reason for change: Data Entry Error	Heather Douds (b) (4)	02 Sep 2020 20:15:16
User entered empty.	Stanley Dublin (b) (4)	02 Sep 2020 14:13:19

US3552273

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 20:14:48
User entered '01 Sep 2020 16:36'	System	02 Sep 2020 20:15:16
User entered empty.	System	02 Sep 2020 14:13:19

US3552273

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:38

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 14:13:19

US3552273

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 14:13:19

US3552273

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:38

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 14:13:19

US3552273

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:38

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 14:13:19

US3552273

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 14:13:19

US3552273

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:38

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 14:13:19

US3552273

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:38

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 14:13:19

US3552273

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 14:13:19

US3552273

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 14:13:19

US3552273

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 14:13:19

US3552273

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 14:13:19

US3552273

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:38

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 14:13:19

US3552273

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 14:13:19

US3552273

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 14:13:19

US3552273

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:38

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 14:13:19

US3552273

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:38

[None](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 14:13:19

US3552273

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: RQ: Response noted, however, please add this AE term to the indication field of the Con Med. Update and reconcile as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 11:27:02
Query 'Per DM CLR: RQ: Response noted, however, please add this AE term to the indication field of the Con Med. Update and reconcile as appropriate.' answered with 'Updated per query request' (Site from DM).	Cassandra Zehenny (b) (4)	23 Oct 2020 15:00:05
User opened query 'Per DM CLR: RQ: Response noted, however, please add this AE term to the indication field of the Con Med. Update and reconcile as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 01:56:43
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 08:34:03
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'Please see con med #3' (Site from DM).	Heather Douds (b) (4)	30 Sep 2020 18:45:17
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 01:52:37
User entered '1'	Stanley Doublin (b) (4)	02 Sep 2020 14:13:19

US3552273

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 14:13:19

US3552273

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:38

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: New Information	Heather Douds (b) (4) (b) (4)	28 Sep 2020 20:14:48
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	02 Sep 2020 20:15:16
User entered 'Unknown (UNKNOWN)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 14:13:19

US3552273

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:38

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 14:13:19

US3552273

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:38

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 14:13:19

US3552273

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:38

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Sep 2020 14:13:19

US3552273

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:38:38

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 14:13:19

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:38:38

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:43:28

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:38:38

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, COMBINATIONS, ATC: ACE INHIBITORS AND DIURETICS, PRODUCT: HYDROCHLOROTHIAZIDE; LISINOPRIL, PRODUCTSYNONYM: LISINOPRIL/HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:58:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 14:58:48
Data point term sent to Coder Coding entries removed.	System Heather Douds (b) (4) (b) (4)	03 Sep 2020 14:57:42 03 Sep 2020 14:57:17
User entered 'LISINOPRIL/hydrochlorothiazide' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	03 Sep 2020 14:57:17
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 17:32:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 17:32:54
Data point term sent to Coder Coding entries removed.	System Heather Douds (b) (4) (b) (4)	02 Sep 2020 17:31:57 02 Sep 2020 17:31:33
User entered 'LISINOPRIL' reason for change: Data Entry Error	Heather Douds (b) (4) (b) (4)	02 Sep 2020 17:31:33
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 15:06:52

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:38:38

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. Data point term sent to Coder User entered 'lisinopail'	Coder Import (b) (4) (b) (4) System Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 15:06:52 02 Sep 2020 13:46:07 02 Sep 2020 13:46:00

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:38:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:46:00

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:38:38

[Indication](#)

Audit	User	Time (GMT)
User entered 'hypertension'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:46:00

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:38:38

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '20 / 25'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:46:00

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:38:38

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:46:00

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:38:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:46:00

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:38:38

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:46:00

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:38:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:46:00

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:38:38

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:46:00

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:38:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:46:00

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered 'un UNK 1990'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:46:00

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:38:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:46:00

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:38:38

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:46:00

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:38:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:46:00

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:38:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:46:00

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:38:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 13:46:00

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:38:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 13:46:00

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:38:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 13:46:00

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:38:38

[Name of Medication](#)

Audit	User	Time (GMT)
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)	02 Sep 2020 13:47:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 13:47:52
Data point term sent to Coder	System	02 Sep 2020 13:47:10
User entered 'omeprazole'	Stanley Doublin (b) (4)	02 Sep 2020 13:46:45

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:38:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:46:45

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:38:38

[Indication](#)

Audit	User	Time (GMT)
User entered 'gastroesophageal reflux disease'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:46:45

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:38:38

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '40'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:46:45

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:38:38

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:46:45

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:38:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:46:45

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:38:38

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:46:45

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:38:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:46:45

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:38:38

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:46:45

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:38:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:46:45

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered 'un UNK 2019'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:46:45

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:38:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:46:45

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:38:38

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:46:45

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:38:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:46:45

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:38:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:46:45

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:38:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 13:46:45

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:38:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 13:46:45

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:38:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 13:46:45

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:38:38

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: ALPRAZOLAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 20:05:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 20:05:41
Data point term sent to Coder	System	23 Oct 2020 15:00:42
Coding entries removed.	Cassandra Zehenny (b) (4)	23 Oct 2020 15:00:30
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: ALPRAZOLAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 13:55:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 13:55:50
Data point term sent to Coder	System	02 Sep 2020 13:54:23
Data point term sent to Coder	System	02 Sep 2020 13:51:14
User entered 'alprazolam'	Stanley Doublin (b) (4)	02 Sep 2020 13:50:27

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:38:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:50:27

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:38:38

[Indication](#)

Audit	User	Time (GMT)
User entered 'ANXIETY and tachycardia' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	23 Oct 2020 15:00:30
User entered 'ANXIETY' reason for change: Data Entry Error	Stanley Doublin (b) (4)	02 Sep 2020 13:54:16
User entered 'moderate anxiety'	Stanley Doublin (b) (4)	02 Sep 2020 13:50:27

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:38:38

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:50:27

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:38:38

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:50:27

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:38:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:50:27

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:38:38

[Frequency](#)

Audit	User	Time (GMT)
User entered 'three times daily (TID)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:50:27

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:38:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:50:27

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:38:38

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:50:27

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:38:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:50:27

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered 'un UNK 2000'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:50:27

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:38:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:50:27

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:38:38

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:50:27

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:38:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:50:27

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:38:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:50:27

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:38:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	02 Sep 2020 13:50:27

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:38:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 13:50:27

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:38:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 13:50:27

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:38:38

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: ANTIVIRALS FOR TREATMENT OF HIV INFECTIONS, COMBINATIONS, PRODUCT: EMTRICITABINE;TENOFVIR ALAFENAMIDE FUMARATE, PRODUCTSYNONYM: DESCOVY - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 14:50:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 14:50:45
Data point term sent to Coder	System	02 Sep 2020 13:54:23
User entered 'descovy'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:54:02

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:38:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:54:02

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:38:38

[Indication](#)

Audit	User	Time (GMT)
User entered 'hiv prophylaxis'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:54:02

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:38:38

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '200/25'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:54:02

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:38:38

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:54:02

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:38:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:54:02

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:38:38

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:54:02

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:38:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:54:02

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:38:38

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:54:02

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:38:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:54:02

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered 'un UNK 2019'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:54:02

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:38:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:54:02

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:38:38

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:54:02

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:38:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:54:02

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:38:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:54:02

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:38:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 13:54:02

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:38:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 13:54:02

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:38:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 13:54:02

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:38:38

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 13:57:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 13:57:52
Data point term sent to Coder	System	02 Sep 2020 13:56:30
User entered 'multivitamin'	Stanley Doublin (b) (4)	02 Sep 2020 13:56:20

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:38:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	11 Nov 2020 16:26:11
User entered 'No (N)'	Stanley Doublin (b) (4)	02 Sep 2020 13:56:20

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:38:38

[Indication](#)

Audit	User	Time (GMT)
User entered 'health promotion'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:56:20

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:38:38

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:56:20

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:38:38

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'tablet (TABLET)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:56:20

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:38:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:56:20

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:38:38

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:56:20

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:38:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:56:20

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:38:38

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:56:20

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:38:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:56:20

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered 'un Mar 2020'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:56:20

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:38:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:56:20

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:38:38

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	02 Sep 2020 13:56:20

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:38:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:56:20

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:38:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	02 Sep 2020 13:56:20

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:38:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 13:56:20

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:38:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 13:56:20

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:38:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 13:56:20

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:38:38

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 13:44:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 13:44:12
Data point term sent to Coder	System	24 Nov 2020 13:42:58
Coding entries removed.	Stanley Doublin (b) (4)	24 Nov 2020 13:42:08
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Oct 2020 17:52:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Oct 2020 17:52:24
Data point term sent to Coder	System	19 Oct 2020 17:51:04
User entered 'influenza vaccine'	Stanley Doublin (b) (4)	19 Oct 2020 17:50:42

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:38:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 17:50:42

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:38:38

[Indication](#)

Audit	User	Time (GMT)
User entered 'INFLUENZA PROPHYLAXIS'	Stanley Dublin (b) (4)	24 Nov 2020 13:42:08
reason for change: Data Entry Error	(b) (4)	
User entered 'prophylaxis'	Stanley Dublin (b) (4)	19 Oct 2020 17:50:42
	(b) (4)	

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:38:38

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 17:50:42

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:38:38

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 17:50:42

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:38:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered 'injection'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 17:50:42

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:38:38

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 17:50:42

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:38:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 17:50:42

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:38:38

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intramuscular (INTRAMUSCULAR)'	Stanley Dublin (b) (4)	19 Oct 2020 17:50:42

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:38:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 17:50:42

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered '16 Oct 2020'	Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 17:50:42

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:38:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 17:50:42

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:38:38

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 17:50:42

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:38:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Oct 2020'	Stanley Dublin (b) (4) (b) (4)	19 Oct 2020 17:50:42

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:38:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	19 Oct 2020 17:50:42

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:38:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 17:50:42

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:38:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 17:50:42

US3552273

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:38:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 17:50:42

US3552273

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:38:38

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020'	Heather Douds (b) (4) (b) (4)	06 Oct 2020 14:05:14

US3552273

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:38:38

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: it appears the AE of Anxiety caused the discontinuation. Please consider selecting 'Adverse Event (Specify) and make all applicable updates.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 09:49:18
User closed query 'Please verify if worsening anxiety (from baseline) should be captured as an AE, since this event lead to investigational product discontinuation. ' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 19:51:43
Query 'Please verify if worsening anxiety (from baseline) should be captured as an AE, since this event lead to investigational product discontinuation. ' answered with 'Anxiety is not an AE as already captured in medical history. Updated appropriately. ' (Site from CRA).	Cassandra Zehenny (b) (4)	19 Nov 2020 16:34:48
User entered 'AE (specify) (ADVERSE EVENT)' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	19 Nov 2020 16:34:26
User opened query 'Please verify if worsening anxiety (from baseline) should be captured as an AE, since this event lead to investigational product discontinuation. ' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 01:54:10
Query 'Per CDM: it appears the AE of Anxiety caused the discontinuation. Please consider selecting 'Adverse Event (Specify) and make all applicable updates.' answered with 'There is no anxiety AE, anxiety is a part of medical history. Entered correctly' (Site from DM).	Cassandra Zehenny (b) (4)	18 Nov 2020 17:59:56
User opened query 'Per CDM: it appears the AE of Anxiety caused the discontinuation. Please consider selecting 'Adverse Event (Specify) and make all applicable updates.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 16:17:39
User entered 'Physician decision (specify) (PHYSICIAN DECISION)'	Heather Douds (b) (4)	06 Oct 2020 14:05:14

US3552273

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:38:38

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

Audit	User	Time (GMT)
User entered 'AE #1' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	19 Nov 2020 16:34:26
User entered 'Anxiety'	Heather Douds (b) (4)	06 Oct 2020 14:05:14