

US3552035 (Prod: Saint Louis University)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:34:01

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US3552035

Form: Participant Creation

Generated On: 26 Nov 2020 09:34:01

[Participant ID](#)

US3552035

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

US3552035

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:34:01

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	14 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:34:01

Date of Birth (MMM yyyy)	(b) (6) 1965
Age	55
Age Units	YEARS
Age (Derived)	55
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 09:34:01

Date of Informed Consent (<i>dd MMM yyyy</i>)	14 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☐
	Amendment 2 ☒
	Amendment 3 ☐
	Amendment 4 ☐
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:34:01

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:34:01

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:34:01

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 2004
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2004
Start Year (derived)	2004
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:34:01

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 1998
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1999
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1998
Start Year (derived)	1998
Stop Month and Year (derived)	JAN 1999
Stop Year (derived)	1999

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:34:01

Condition	ATTENTION DEFICIT DISORDER
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:34:01

Condition	REFLUX DISEASE
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:34:01

Condition	BARRETTS ESOPHAGUST
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:34:01

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2006
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 2006
Start Year (derived)	2006
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:34:01

Condition	INSOMNIA
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:34:01

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

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:34:01

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

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Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:34:01

Condition	L4-L5 DEGENERATIVE DISK
Start date (dd MMM yyyy)	UN UNK 2001
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2001
Start Year (derived)	2001
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:01

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	14 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	10:54 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 10:54
Height (<i>xxx.x</i>)	73 in
Weight (<i>xxx.x</i>)	216 lb
BMI (<i>xxx.x</i>)	28.55735 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 09:34:01

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:01

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified 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

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:01

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 09:34:01

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	14 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:34:01

What was the date of randomization? (dd MMM yyyy) 14 AUG 2020

What was the participant's randomization number? 104082

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 09:34:01

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 09:34:01

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)	14 AUG 2020
Time of assessment (00:00-23:59)	10:54 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 10:54
Temperature (xxx.x)	97.8 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 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 09:34:01

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)	14 AUG 2020
Time of assessment (00:00-23:59)	12:53 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 12:53
Temperature (xxx.x)	97.7 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 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: Physical Examination

Generated On: 26 Nov 2020 09:34:01

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 09:34:01

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) 14 AUG 2020

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

Treatment Date and Time (derived) 14 AUG 2020 12:23

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 09:34:01

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	14 AUG 2020
Collection time (<i>00:00-23:59</i>)	11:28 (24 HR)
Collection date and time (derived)	14 AUG 2020 11:28

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:34:01

Collection date (<i>dd MMM yyyy</i>)			14 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:33	14 AUG 2020 11:33
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:34:01

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 09:34:01

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 13:03

PC Open Date & Time

14 AUG 2020 12:43

PC Close Date & Time

14 AUG 2020 15:13

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:34:01

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 96.8 °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	15 AUG 2020 10:44
PC Open Date & Time	14 AUG 2020 16:08
PC Close Date & Time	15 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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

16 AUG 2020 00:23

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 22:43

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 AUG 2020 02:12

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 AUG 2020 00:55

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:34:01

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

97.4 °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

20 AUG 2020 02:35

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 AUG 2020 23:38

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

10

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

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 AUG 2020 13:05

PC Open Date & Time

14 AUG 2020 12:43

PC Close Date & Time

14 AUG 2020 15:13

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:34:01

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

15 AUG 2020 10:54

PC Open Date & Time

14 AUG 2020 16:08

PC Close Date & Time

15 AUG 2020 11:59

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:34:01

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

16 AUG 2020 00:25

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:34:01

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

16 AUG 2020 22:43

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:34:01

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

18 AUG 2020 02:13

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:34:01

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

19 AUG 2020 00:56

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:34:01

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

20 AUG 2020 02:35

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:34:01

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

20 AUG 2020 23:38

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:34:01

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

No ☒

Yes ☐

PC Time stamp	14 AUG 2020 13:06
PC Open Date & Time	14 AUG 2020 12:43
PC Close Date & Time	14 AUG 2020 15:13

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:34:01

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

No ☒

Yes ☐

PC Time stamp	15 AUG 2020 10:55
PC Open Date & Time	14 AUG 2020 16:08
PC Close Date & Time	15 AUG 2020 11:59

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:34:01

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 ☒

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:34:01

Yes ☐	
PC Time stamp	16 AUG 2020 00:26
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:34:01

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 ☒

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:34:01

Yes ☐	
PC Time stamp	16 AUG 2020 22:43
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:34:01

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 ☒

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:34:01

Yes ☐	
PC Time stamp	18 AUG 2020 02:13
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:34:01

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 ☒

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:34:01

Yes ☐	
PC Time stamp	19 AUG 2020 00:56
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:34:01

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 ☒

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:34:01

Yes ☐	
PC Time stamp	20 AUG 2020 02:35
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:34:01

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 ☒

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:34:01

Yes ☐	
PC Time stamp	20 AUG 2020 23:39
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3552035

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552035

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552035

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552035

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552035

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552035

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552035

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:34:01

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	17 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:01

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	17 SEP 2020
Time of assessment (00:00-23:59)	12:45 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 12:45
Temperature (xxx.x)	97.7 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:01

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	

US3552035

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:34:01

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 SEP 2020

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

US3552035

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:34:01

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

SHINGLES INFECTION

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? _____

US3552035

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:34:01

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	17 SEP 2020
Collection time (<i>00:00-23:59</i>)	13:11 (24 HR)
Collection date and time (derived)	17 SEP 2020 13:11

US3552035

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:34:01

Collection date (dd MMM yyyy)			17 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:14	17 SEP 2020 13:14
Nasopharyngeal Swab 2	No		

US3552035

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552035

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552035

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552035

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552035

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552035

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552035

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552035

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:34:01

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	12 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3552035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:01

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

US3552035

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:34:01

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.

US3552035

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:34:01

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

12 OCT 2020

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

11:00 (24 HR)

Collection date and time (derived)

12 OCT 2020 11:00

US3552035

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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	14 OCT 2020 00:50:40
Patient Cloud Open Date & Time	14 OCT 2020 00:01
Patient Cloud Close Date & Time	18 OCT 2020 23:59

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

22 OCT 2020 14:50:50

Patient Cloud Open Date & Time

21 OCT 2020 00:01

Patient Cloud Close Date & Time

25 OCT 2020 23:59

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

28 OCT 2020 13:24:00

Patient Cloud Open Date & Time

28 OCT 2020 00:01

Patient Cloud Close Date & Time

01 NOV 2020 23:59

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 NOV 2020 23:49:08
Patient Cloud Open Date & Time	11 NOV 2020 00:01
Patient Cloud Close Date & Time	15 NOV 2020 23:59

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

DAY 99

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

No ☒

Yes ☐

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

18 NOV 2020 00:01:24

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

[Patient Cloud Close Date & Time](#)

15 OCT 2020 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

22 OCT 2020 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

29 OCT 2020 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

05 NOV 2020 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

12 NOV 2020 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

19 NOV 2020 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 NOV 2020 02:02:36

Patient Cloud Open Date & Time

22 NOV 2020 00:01

Patient Cloud Close Date & Time

26 NOV 2020 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

03 DEC 2020 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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

Date and time of submission

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06 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

10 DEC 2020 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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

Date and time of submission

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13 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

17 DEC 2020 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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24 DEC 2020 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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

Date and time of submission

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27 DEC 2020 00:01

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US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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07 JAN 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JAN 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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 JAN 2021 00:01

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21 JAN 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JAN 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 FEB 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

11 FEB 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

18 FEB 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

25 FEB 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

04 MAR 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAR 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAR 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAR 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

01 APR 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

08 APR 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

15 APR 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

22 APR 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

29 APR 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

14 OCT 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

16 DEC 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

30 DEC 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAR 2022 00:01

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10 MAR 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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

Date and time of submission

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13 MAR 2022 00:01

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17 MAR 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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24 MAR 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAR 2022 00:01

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31 MAR 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 APR 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 APR 2022 00:01

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21 APR 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 APR 2022 00:01

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28 APR 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

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05 MAY 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

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12 MAY 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2022 23:59

US3552035

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552035

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:01

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3552035

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:34:01

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 ☐

US3552035

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:34:01

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3552035

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:34:01

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:01

AEID	
Adverse event	SHINGLES
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	04 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	21 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☒ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False
v6.020 DTW (1102)	309 of 1437

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:01

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)	_____

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:34:01

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

Yes ☒

No ☐

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

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:34:01

Name of Medication	SERTRALINE
Prophylaxis	Yes ☐ No ☒
Indication	ANXIETY
Dose per administration	150
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 ☐

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:34:01

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

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:34:01

Name of Medication	METHYLPHENIDATE
Prophylaxis	Yes ☐ No ☒
Indication	ATTENTION DEFICIT DISORDER
Dose per administration	54
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 ☐

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:34:01

	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 2005
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	☒

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:34:01

Name of Medication	OMEPRAZOLE
Prophylaxis	Yes ☐ No ☒
Indication	REFLUX DISEASE
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 ☐

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:34:01

	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 2010
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	☒

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:34:01

Name of Medication	NAPROXEN
Prophylaxis	Yes ☐ No ☒
Indication	BACK PAIN
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 ☐

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:34:01

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

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:34:01

Name of Medication	LUNESTA
Prophylaxis	Yes ☐ No ☒
Indication	INSOMNIA
Dose per administration	0.5
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☒ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:34:01

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

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:34:01

Name of Medication	PREDNISONE
Prophylaxis	Yes ☐ No ☒
Indication	SHINGLES
Dose per administration	24-4
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 ☐

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:34:01

	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)		04 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		09 SEP 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:34:01

Name of Medication	VALACYCLOVIR
Prophylaxis	Yes ☐ No ☒
Indication	SHINGLES
Dose per administration	1 MG
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 ☐

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:34:01

	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)		04 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		14 SEP 2020
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	☒

US3552035

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:34:01

Were any concomitant procedures performed?

Yes ☐

No ☐

If yes, please complete Concomitant Procedures form.

US3552035

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:34:01

Date of dosing discontinuation (dd MMM yyyy)

17 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

US3552035

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:34:01

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

US3552035 (Prod: Saint Louis University)

US3552035

Form: Participant Creation

Generated On: 26 Nov 2020 09:34:01

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3552035'	RWS_ENDPOINT ENDPOINT (b) (4) 	14 Aug 2020 16:54:30

US3552035

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:34:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:38:33
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:03:11

US3552035

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:38:33
User entered '14 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 16:54:31

US3552035

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:38:33
User entered 'Clinic (Clinic)'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:03:11

US3552035

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:34:01

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	14 Aug 2020 20:03:11

US3552035

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:38:50
User entered (b) (6) 1965'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 16:54:31

US3552035

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:34:01

[Age](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:38:50
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 20:03:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Aug 2020 20:03:42
User closed query 'Age does not fit Cohort. Please review and update.' (Site from System).	System	14 Aug 2020 20:03:42
User entered '55' reason for change: Data Entry Error	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:03:42
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 20:03:22
User opened query 'Age does not fit Cohort. Please review and update.' (Site from System).	System	14 Aug 2020 20:03:22
User entered empty.	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:03:22

US3552035

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:34:01

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	14 Aug 2020 20:03:42
User entered empty.	System	14 Aug 2020 20:03:22

US3552035

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:34:01

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '55'	System	14 Aug 2020 17:04:23

US3552035

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:34:01

[Sex](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:38:50
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 20:03:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Aug 2020 20:03:47
User entered 'Male (M)' reason for change: Data Entry Error	Mikayla Frye (b) (4)	14 Aug 2020 20:03:47
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 20:03:22
User entered empty.	Mikayla Frye (b) (4)	14 Aug 2020 20:03:22

US3552035

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:34:01

[Ethnicity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:38:50
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:03:22

US3552035

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:34:01

[White](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:38:50
User entered '1'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:03:22

US3552035

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:34:01

[Black](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:38:50
User entered '0'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:03:22

US3552035

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:34:01

[Asian](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:38:50
User entered '0'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:03:22

US3552035

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:34:01

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:38:50
User entered '0'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:03:22

US3552035

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:34:01

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:38:50
User entered '0'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:03:22

US3552035

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:34:01

[Other](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:38:50
User entered '0'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:03:22

US3552035

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:34:01

[If race is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:38:50
User entered empty.	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:03:22

US3552035

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:34:01

[Unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:38:50
User entered '0'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:03:22

US3552035

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:34:01

[Not reported](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:38:50
User entered '0'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:03:22

US3552035

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:39:05
User entered '14 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 17:04:23

US3552035

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	14 Aug 2020 17:04:23

US3552035

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
User entered '2020'	System	14 Aug 2020 17:04:23

US3552035

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:34:01

[Protocol Version](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:39:05
User entered 'Amendment 2 (2)'	(b) (4), (b) (6)	14 Aug 2020 17:04:23

US3552035

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:39:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 17:04:23

US3552035

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:39:05
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 17:04:23

US3552035

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:34:01

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:39:05
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 17:04:23

US3552035

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:34:01

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:39:05
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 17:04:23

US3552035

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:34:01

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:39:05
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 16:54:31

US3552035

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:34:01

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 17:04:33

US3552035

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:39:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 17:04:33

US3552035

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:34:01

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:40:37
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:04:34

US3552035

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:34:01

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:42:20
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 00:10:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 00:10:52
Data point term sent to Coder	System	14 Aug 2020 20:05:37
User entered 'Anxiety'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:05:03

US3552035

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:42:20
User entered 'UN UNK 2004'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:05:03

US3552035

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:34:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:42:20
User entered '0'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:05:03

US3552035

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:34:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:42:20
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:05:03

US3552035

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:42:20
User entered empty.	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:05:03

US3552035

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:34:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:42:20
User entered '0'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:05:03

US3552035

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
User entered 'Jan 2004'	System	14 Aug 2020 20:05:03

US3552035

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
User entered '2004'	System	14 Aug 2020 20:05:03

US3552035

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 20:05:03

US3552035

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 20:05:03

US3552035

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:34:01

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:42:20
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 00:11:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 00:11:07
Data point term sent to Coder	System	14 Aug 2020 20:06:38
User entered 'Depression'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:05:38

US3552035

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:42:20
User entered 'UN UNK 1998'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:05:38

US3552035

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:34:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:42:20
User entered '0'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:05:38

US3552035

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:34:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:42:20
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:05:38

US3552035

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:42:20
User entered 'UN UNK 1999'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:05:38

US3552035

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:34:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:42:20
User entered '0'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:05:38

US3552035

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
User entered 'Jan 1998'	System	14 Aug 2020 20:05:38

US3552035

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
User entered '1998'	System	14 Aug 2020 20:05:38

US3552035

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
User entered 'Jan 1999'	System	14 Aug 2020 20:05:38

US3552035

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
User entered '1999'	System	14 Aug 2020 20:05:38

US3552035

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:34:01

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:42:20
User coded data point as SOC: Psychiatric disorders, HLGT: Cognitive and attention disorders and disturbances, HLT: Attention deficit and disruptive behaviour disorders, PT: Attention deficit hyperactivity disorder, LLT: Attention deficit disorder - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 00:11:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 00:11:16
Data point term sent to Coder	System	14 Aug 2020 20:08:46
User entered 'Attention Deficit Disorder'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:08:10

US3552035

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:42:20
User entered 'UN UNK 2005'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:08:10

US3552035

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:34:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:42:20
User entered '0'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:08:10

US3552035

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:34:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:42:20
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:08:10

US3552035

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:42:20
User entered empty.	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:08:10

US3552035

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:34:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:42:20
User entered '0'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:08:10

US3552035

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
User entered 'Jan 2005'	System	14 Aug 2020 20:08:10

US3552035

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
User entered '2005'	System	14 Aug 2020 20:08:10

US3552035

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 20:08:10

US3552035

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 20:08:10

US3552035

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:34:01

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:42:20
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: Gastrooesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 06:26:10
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 06:26:10
Data point term sent to Coder	System	14 Aug 2020 20:08:46
User entered 'Reflux disease'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:08:40

US3552035

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:42:20
User entered 'UN UNK 2010'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:08:40

US3552035

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:34:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:42:20
User entered '0'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:08:40

US3552035

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:34:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:42:20
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:08:40

US3552035

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:42:20
User entered empty.	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:08:40

US3552035

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:34:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:42:20
User entered '0'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:08:40

US3552035

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	14 Aug 2020 20:08:40

US3552035

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
User entered '2010'	System	14 Aug 2020 20:08:40

US3552035

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 20:08:40

US3552035

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 20:08:40

US3552035

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:34:01

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:42:20
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal conditions NEC, HLT: Gastrointestinal mucosal dystrophies and secretion disorders, PT: Barrett's oesophagus, LLT: Barrett's oesophagus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 00:22:14
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 00:22:14
Data point term sent to Coder	System	14 Aug 2020 22:38:58
User entered 'BARRETS ESOPHAGUS' reason for change: Data Entry Error	Joan Siegner (b) (4) (b) (4)	14 Aug 2020 22:38:34
Data point term sent to Coder	System	14 Aug 2020 20:09:47
User entered 'Barrets Esophagus'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:09:03

US3552035

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:42:20
User entered 'UN UNK 2010'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:09:03

US3552035

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:34:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:42:20
User entered '0'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:09:03

US3552035

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:34:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:42:20
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:09:03

US3552035

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:42:20
User entered empty.	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:09:03

US3552035

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:34:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:42:20
User entered '0'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:09:03

US3552035

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	14 Aug 2020 20:09:03

US3552035

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
User entered '2010'	System	14 Aug 2020 20:09:03

US3552035

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 20:09:03

US3552035

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 20:09:03

US3552035

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:34:01

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:42:20
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 00:22:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 00:22:13
Data point term sent to Coder	System	14 Aug 2020 22:38:58
User entered 'SEASONal ALLERGIES' reason for change: Data Entry Error	Joan Siegner (b) (4) (b) (4)	14 Aug 2020 22:38:49
Data point term sent to Coder	System	14 Aug 2020 20:09:48
User entered 'Season allergies'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:09:26

US3552035

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:42:20
User entered 'UN UNK 2006'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:09:26

US3552035

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:34:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:42:20
User entered '0'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:09:26

US3552035

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:34:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:42:20
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:09:26

US3552035

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:42:20
User entered empty.	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:09:26

US3552035

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:34:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:42:20
User entered '0'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:09:26

US3552035

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
User entered 'Jan 2006'	System	14 Aug 2020 20:09:26

US3552035

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
User entered '2006'	System	14 Aug 2020 20:09:26

US3552035

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 20:09:26

US3552035

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 20:09:26

US3552035

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:34:01

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:42:20
User coded data point as SOC: Psychiatric disorders, HLGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 00:11:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	15 Aug 2020 00:11:23
Data point term sent to Coder	System	14 Aug 2020 20:09:49
User entered 'Insomnia'	Mikayla Frye (b) (4)	14 Aug 2020 20:09:48
	(b) (4)	

US3552035

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:42:20
User entered 'UN UNK 2010'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:09:48

US3552035

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:34:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:42:20
User entered '0'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:09:48

US3552035

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:34:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:42:20
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:09:48

US3552035

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:42:20
User entered empty.	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:09:48

US3552035

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:34:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:42:20
User entered '0'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:09:48

US3552035

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	14 Aug 2020 20:09:48

US3552035

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
User entered '2010'	System	14 Aug 2020 20:09:48

US3552035

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 20:09:48

US3552035

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 20:09:48

US3552035

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:34:01

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:02
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Herpes zoster, LLT: Shingles - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 20:17:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	17 Sep 2020 20:17:40
Data point term sent to Coder	System	17 Sep 2020 20:16:52
User entered 'shingles'	Joan Siegner (b) (4)	17 Sep 2020 20:16:16

US3552035

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:04
User entered 'un Oct 2017'	Joan Siegner (b) (4)	17 Sep 2020 20:16:16

US3552035

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:34:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:05
User entered '0'	Joan Siegner (b) (4)	17 Sep 2020 20:16:16

US3552035

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:34:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:07
User entered 'No (N)'	Joan Siegner (b) (4)	17 Sep 2020 20:16:16

US3552035

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:09
User entered 'un Nov 2017'	Joan Siegner (b) (4)	17 Sep 2020 20:16:16

US3552035

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:34:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:11
User entered '0'	Joan Siegner (b) (4)	17 Sep 2020 20:16:16

US3552035

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
User entered 'Oct 2017'	System	17 Sep 2020 20:16:16

US3552035

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
User entered '2017'	System	17 Sep 2020 20:16:16

US3552035

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
User entered 'Nov 2017'	System	17 Sep 2020 20:16:16

US3552035

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
User entered '2017'	System	17 Sep 2020 20:16:16

US3552035

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:34:01

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:15
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Back pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 00:00:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 00:00:58
Data point term sent to Coder	System	08 Oct 2020 19:22:01
User entered 'back pain'	Stanley Doublin (b) (4) (b) (4)	08 Oct 2020 19:21:40

US3552035

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:16
User entered 'un Oct 2017'	Stanley Doublin (b) (4) (b) (4)	08 Oct 2020 19:21:40

US3552035

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:34:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:18
User entered '0'	Stanley Doublin (b) (4) (b) (4)	08 Oct 2020 19:21:40

US3552035

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:34:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:20
User entered 'Yes (Y)'	Stanley Dublin (b) (4) (b) (4)	08 Oct 2020 19:21:40

US3552035

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:21
User entered empty.	Stanley Doublin (b) (4) (b) (4)	08 Oct 2020 19:21:40

US3552035

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:34:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:23
User entered '0'	Stanley Doublin (b) (4) (b) (4)	08 Oct 2020 19:21:40

US3552035

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
User entered 'Oct 2017'	System	08 Oct 2020 19:21:40

US3552035

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
User entered '2017'	System	08 Oct 2020 19:21:40

US3552035

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
User entered empty.	System	08 Oct 2020 19:21:40

US3552035

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
User entered empty.	System	08 Oct 2020 19:21:40

US3552035

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:34:01

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc degeneration, LLT: Lumbar disc degeneration - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 08:20:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 08:20:54
User closed query 'Please add that it is L4-5 to reconcile with source Thank you! ' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 22:04:29
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:28
Data point term sent to Coder	System	27 Oct 2020 15:39:31
Query 'Please add that it is L4-5 to reconcile with source Thank you! ' answered with 'updated per query request' (Site from CRA).	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 15:39:18
DataPoint Un-verified.	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 15:38:53
Coding entries removed.	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 15:38:53
User entered 'L4-L5 DEGENERATIVE DISK' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4) (b) (4)	27 Oct 2020 15:38:53
User closed query 'Per DM CLR: Please specify the location (bilateral, left, right) and/or type of DEGENERATIVE DISK. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 10:06:02
User opened query 'Please add that it is L4-5 to reconcile with source Thank you! ' (Site from CRA).	(b) (4), (b) (6)	26 Oct 2020 19:17:02
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 19:11:53

US3552035

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:34:01

[Condition](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please specify the location (bilateral, left, right) and/or type of DEGENERATIVE DISK. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed 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)	23 Oct 2020 14:27:44
User opened query 'Per DM CLR: Please specify the location (bilateral, left, right) and/or type of DEGENERATIVE DISK. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 20:49:44
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc degeneration, LLT: Degenerative disc disease - version MedDRA\23.0.	Coder Import (b) (4)	12 Oct 2020 19:02:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	12 Oct 2020 19:02:20
Data point term sent to Coder	System	12 Oct 2020 19:01:11
User entered 'degenerative disk'	Stanley Doublin (b) (4)	12 Oct 2020 19:00:59

US3552035

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 19:15:31
User entered 'un UNK 2001'	Stanley Doublin (b) (4) (b) (4)	12 Oct 2020 19:00:59

US3552035

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:34:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 19:15:51
User entered '0'	Stanley Doublin (b) (4) (b) (4)	12 Oct 2020 19:00:59

US3552035

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:34:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 19:15:54
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	12 Oct 2020 19:00:59

US3552035

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 19:15:56
User entered empty.	Stanley Doublin (b) (4) (b) (4)	12 Oct 2020 19:00:59

US3552035

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:34:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 19:15:57
User entered '0'	Stanley Doublin (b) (4) (b) (4)	12 Oct 2020 19:00:59

US3552035

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
User entered 'Jan 2001'	System	12 Oct 2020 19:00:59

US3552035

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
User entered '2001'	System	12 Oct 2020 19:00:59

US3552035

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 19:00:59

US3552035

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 19:00:59

US3552035

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:42:56
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:10:42

US3552035

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:42:56
User entered '14 Aug 2020'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:10:42

US3552035

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:42:56
User entered '10:54'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:10:42

US3552035

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
User entered '14 Aug 2020 10:54'	System	14 Aug 2020 20:10:42

US3552035

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:42:56
User entered '73' in	Mikayla Frye (b) (4)	14 Aug 2020 20:10:42
DataPoint set to visible.	(b) (4) System	14 Aug 2020 17:04:33

US3552035

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:42:56
User entered '216' lb	Mikayla Frye (b) (4)	14 Aug 2020 20:10:42
DataPoint set to visible.	(b) (4) System	14 Aug 2020 17:04:33

US3552035

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:01

BMI (xxx.x)

Audit	User	Time (GMT)
Amendment Manager: User entered '28.55735'	System	16 Sep 2020 23:57:28
User entered '28.6'	System	14 Aug 2020 20:10:42
DataPoint set to visible.	System	14 Aug 2020 17:04:33

US3552035

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:01

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	14 Aug 2020 20:10:42
DataPoint set to visible.	System	14 Aug 2020 17:04:33

US3552035

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:42:56
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:10:42

US3552035

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:01

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:42:56
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 11:28:24
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	Mikayla Frye (b) (4)	14 Aug 2020 20:10:46
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	14 Aug 2020 20:10:42
User entered empty.	System	14 Aug 2020 20:10:42
	Mikayla Frye (b) (4)	14 Aug 2020 20:10:42
	(b) (4)	

US3552035

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:01

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:42:56
User entered empty.	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:10:42

US3552035

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:42:56
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:10:42

US3552035

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:01

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	14 Aug 2020 20:10:42

US3552035

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:42:56
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:10:42

US3552035

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	14 Aug 2020 20:10:42

US3552035

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:42:56
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:10:42

US3552035

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Aug 2020 20:10:42

US3552035

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:42:56
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:10:42

US3552035

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Aug 2020 20:10:42

US3552035

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:34:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:43:54
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:10:56

US3552035

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:43:54
User entered '14 Aug 2020'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:10:56

US3552035

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:44:39
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:11:49

US3552035

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:44:39
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:11:49

US3552035

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:44:39
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:11:49

US3552035

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:44:39
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:11:49

US3552035

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:44:39
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:11:49

US3552035

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:44:39
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:11:49

US3552035

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:44:39
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:11:49

US3552035

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:44:39
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:11:49

US3552035

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:44:39
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:11:49

US3552035

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:44:39
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:11:49

US3552035

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:44:39
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:11:49

US3552035

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:01

Other

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:44:39
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:11:49

US3552035

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:01

[Specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:44:39
User entered empty.	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:11:49

US3552035

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:01

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:11:49

US3552035

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:01

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:44:39
User entered '0'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:11:49

US3552035

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:44:39
User entered '0'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:11:49

US3552035

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:44:39
User entered '0'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:11:49

US3552035

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:44:39
User entered '0'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:11:49

US3552035

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:44:39
User entered '1'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:11:49

US3552035

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:01

Other

Audit	User	Time (GMT)
User entered '0'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:11:49

US3552035

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:34:01

[Specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:44:39
User entered empty.	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:11:49

US3552035

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:34:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:45:10
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:12:00

US3552035

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:45:10
User entered '14 Aug 2020'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:12:00

US3552035

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:45:10
User entered 'Clinic (Clinic)'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:12:00

US3552035

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:34:01

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	14 Aug 2020 20:12:00

US3552035

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:45:24
User entered '14 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 16:54:57

US3552035

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 19:17:29
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 04:35:29
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:35:28
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Aug 2020 16:54:57
User entered '104082' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 16:54:57

US3552035

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:45:25
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 16:54:57

US3552035

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:45:27
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:12:17

US3552035

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:45:30
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:12:17

US3552035

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:45:32
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:12:17

US3552035

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:45:34
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:12:17

US3552035

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:34:01

[Liver Disease](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:45:36
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:12:17

US3552035

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 19:17:31
User entered 'No (N)'	Stanley Doublin (b) (4)	21 Sep 2020 17:00:36
Amendment Manager: DataPoint set to visible.	(b) (4)	19 Sep 2020 10:21:09
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:19:46

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:34:01

[Height](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:46:34
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:14:02

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:34:01

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:46:34
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:14:02

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:34:01

[Height](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:46:34
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:14:02

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:34:01

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:46:34
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:14:02

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:01

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:14:02

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:46:34
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:14:02

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:46:34
User entered '14 Aug 2020'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:14:02

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:46:34
User entered '10:54'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:14:02

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
User entered '14 Aug 2020 10:54'	System	14 Aug 2020 20:14:02

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:01

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:46:34
User entered '97.8' F	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:14:02

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:01

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:46:34
User entered 'Oral (Oral)'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:14:02

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:01

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:46:34
User entered empty.	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:14:02

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:46:34
User entered '68'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:14:02

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:01

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	14 Aug 2020 20:14:02

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:46:34
User entered '18'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:14:02

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	14 Aug 2020 20:14:02

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:46:34
User entered '127'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:14:02

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Aug 2020 20:14:02

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:46:34
User entered '80'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:14:02

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Aug 2020 20:14:02

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:34:01

[Height](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:46:34
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:14:02

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:34:01

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:46:34
User entered missing code ND - Not Done.	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:14:02

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:01

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:14:02

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:46:34
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:14:02

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:46:34
User entered '14 Aug 2020'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:14:02

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 04:35:25
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:46:34
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Time is correct as entered.' (Site from System).	Mikayla Frye (b) (4)	14 Aug 2020 20:14:25
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4)	14 Aug 2020 20:14:15
User closed query 'Data is required. Please provide.' (Site from System).	System	14 Aug 2020 20:14:15
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	14 Aug 2020 20:14:15
User entered '12:53' reason for change: Data Entry Error	Mikayla Frye (b) (4)	14 Aug 2020 20:14:15
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	14 Aug 2020 20:14:02
User entered empty.	Mikayla Frye (b) (4)	14 Aug 2020 20:14:02
	(b) (4)	

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:53'	System	14 Aug 2020 20:14:15
User entered empty.	System	14 Aug 2020 20:14:02

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:46:34
User entered '97.7' F	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:14:02

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:01

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:46:34
User entered 'Oral (Oral)'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:14:02

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:01

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:46:34
User entered empty.	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:14:02

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:46:34
User entered '60'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:14:02

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:01

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	14 Aug 2020 20:14:02

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:46:34
User entered '20'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:14:02

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	14 Aug 2020 20:14:02

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:46:34
User entered '128'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:14:02

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Aug 2020 20:14:02

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:46:34
User entered '77'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:14:02

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Aug 2020 20:14:02

US3552035

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:34:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:46:43
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	18 Aug 2020 19:07:02

US3552035

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:46:43
User entered empty.	Stanley Doublin (b) (4) (b) (4)	18 Aug 2020 19:07:02

US3552035

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:34:01

[Was study treatment given?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:46:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 17:26:31

US3552035

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:34:01

[If No, reason not given](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:46:55
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 17:26:31

US3552035

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:46:55
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 17:26:31

US3552035

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:34:01

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	14 Aug 2020 17:26:31

US3552035

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:46:55
User entered '14 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 17:26:31

US3552035

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:46:55
User entered '12:23'	(b) (4), (b) (6)	14 Aug 2020 17:26:31

US3552035

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:23'	System	14 Aug 2020 17:26:31

US3552035

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:46:55
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	14 Aug 2020 17:26:31

US3552035

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:46:55
User entered 'ONCE'	System	14 Aug 2020 17:26:31

US3552035

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	14 Aug 2020 17:26:31

US3552035

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:34:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:47:07
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:14:45

US3552035

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:47:07
User entered '14 Aug 2020'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:14:45

US3552035

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:47:07
User entered '11:28'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:14:45

US3552035

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:28'	System	14 Aug 2020 20:14:45

US3552035

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:47:18
User entered '14 Aug 2020'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:14:59

US3552035

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:34:01

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:14:59

US3552035

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:34:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:47:18
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:14:59

US3552035

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:47:18
User entered '11:33'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:14:59

US3552035

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:33'	System	14 Aug 2020 20:14:59

US3552035

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:34:01

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:14:59

US3552035

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:34:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:47:18
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:14:59

US3552035

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Aug 2020 17:47:18
User entered empty.	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:14:59

US3552035

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 20:14:59

US3552035

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:48:22
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	21 Aug 2020 20:35:07

US3552035

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:34:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 20:35:07

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 17:26:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:34:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-14T13:03:37', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'e2ac06c3-5363-44e3-b25f-9372daee10c7'	System	14 Aug 2020 18:04:03
User entered 'Yes (Y)'	System	14 Aug 2020 18:04:03

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:34:01

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-14T13:03:47', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'e2ac06c3-5363-44e3-b25f-9372daee10c7'	System	14 Aug 2020 18:04:03
User entered '97.7'	System	14 Aug 2020 18:04:03

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-14T13:03:50', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'e2ac06c3-5363-44e3-b25f-9372daee10c7'	System	14 Aug 2020 18:04:03
User entered 'No (N)'	System	14 Aug 2020 18:04:03

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:34:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-14T13:03:58', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'e2ac06c3-5363-44e3-b25f-9372daee10c7'	System	14 Aug 2020 18:04:03
User entered '14 Aug 2020 13:03'	System	14 Aug 2020 18:04:03

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:34:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:43'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:34:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 15:13'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 17:26:31
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:34:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-15T10:42:54', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'ad799a5e-0b49-4670-831e-0669a4363522'	System	15 Aug 2020 15:44:03
User entered 'Yes (Y)'	System	15 Aug 2020 15:44:03

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:34:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-15T10:43:06', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'ad799a5e-0b49-4670-831e-0669a4363522'	System	15 Aug 2020 15:44:03
User entered '96.8'	System	15 Aug 2020 15:44:03

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-15T10:43:12', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'ad799a5e-0b49-4670-831e-0669a4363522'	System	15 Aug 2020 15:44:03
User entered 'No (N)'	System	15 Aug 2020 15:44:03

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:34:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-15T10:44:01', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'ad799a5e-0b49-4670-831e-0669a4363522'	System	15 Aug 2020 15:44:03
User entered '15 Aug 2020 10:44'	System	15 Aug 2020 15:44:03

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:34:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 16:08'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:34:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 17:26:31
User entered 'Day 2'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:34:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T00:22:59', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '0601e31d-9a95-48e1-90df-d06d132a1b1f'	System	16 Aug 2020 05:23:22
User entered 'Yes (Y)'	System	16 Aug 2020 05:23:22

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:34:01

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T00:23:14', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '0601e31d-9a95-48e1-90df-d06d132a1b1f'	System	16 Aug 2020 05:23:22
User entered '97.4'	System	16 Aug 2020 05:23:22

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T00:23:17', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '0601e31d-9a95-48e1-90df-d06d132a1b1f'	System	16 Aug 2020 05:23:22
User entered 'No (N)'	System	16 Aug 2020 05:23:22

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:34:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T00:23:21', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '0601e31d-9a95-48e1-90df-d06d132a1b1f'	System	16 Aug 2020 05:23:22
User entered '16 Aug 2020 00:23'	System	16 Aug 2020 05:23:22

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:34:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:34:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 17:26:31
User entered 'Day 3'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:34:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T22:41:56', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'c9ff5cb6-d317-4859-a985-90b72802a044'	System	17 Aug 2020 03:43:05
User entered 'Yes (Y)'	System	17 Aug 2020 03:43:05

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:34:01

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T22:42:56', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'c9ff5cb6-d317-4859-a985-90b72802a044'	System	17 Aug 2020 03:43:05
User entered '97.7'	System	17 Aug 2020 03:43:05

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T22:42:59', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'c9ff5cb6-d317-4859-a985-90b72802a044'	System	17 Aug 2020 03:43:05
User entered 'No (N)'	System	17 Aug 2020 03:43:05

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:34:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T22:43:01', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'c9ff5cb6-d317-4859-a985-90b72802a044'	System	17 Aug 2020 03:43:05
User entered '16 Aug 2020 22:43'	System	17 Aug 2020 03:43:05

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:34:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:34:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 17:26:31
User entered 'Day 4'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:34:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-18T02:09:11', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '08870f86-e5cb-439b-a412-d58be6d4b212'	System	18 Aug 2020 07:13:00
User entered 'Yes (Y)'	System	18 Aug 2020 07:13:00

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:34:01

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-18T02:12:49', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '08870f86-e5cb-439b-a412-d58be6d4b212'	System	18 Aug 2020 07:13:00
User entered '96.9'	System	18 Aug 2020 07:13:00

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-18T02:12:53', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '08870f86-e5cb-439b-a412-d58be6d4b212'	System	18 Aug 2020 07:13:00
User entered 'No (N)'	System	18 Aug 2020 07:13:00

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:34:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-18T02:12:56', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '08870f86-e5cb-439b-a412-d58be6d4b212'	System	18 Aug 2020 07:13:00
User entered '18 Aug 2020 02:12'	System	18 Aug 2020 07:13:00

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:34:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:34:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 17:26:31
User entered 'Day 5'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:34:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-19T00:55:15', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '37dbf7ed-50b8-49fb-9b69-1bdd640d525c'	System	19 Aug 2020 05:55:58
User entered 'Yes (Y)'	System	19 Aug 2020 05:55:58

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:34:01

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-19T00:55:47', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '37dbf7ed-50b8-49fb-9b69-1bdd640d525c' User entered '97.6'	System	19 Aug 2020 05:55:58
	System	19 Aug 2020 05:55:58

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-19T00:55:50', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '37dbf7ed-50b8-49fb-9b69-1bdd640d525c'	System	19 Aug 2020 05:55:58
User entered 'No (N)'	System	19 Aug 2020 05:55:58

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:34:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-19T00:55:53', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '37dbf7ed-50b8-49fb-9b69-1bdd640d525c'	System	19 Aug 2020 05:55:58
User entered '19 Aug 2020 00:55'	System	19 Aug 2020 05:55:58

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:34:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:34:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 17:26:31
User entered 'Day 6'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:34:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T02:34:57', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '960a4424-f519-46e8-8536-c0079b5caad9'	System	20 Aug 2020 07:35:13
User entered 'Yes (Y)'	System	20 Aug 2020 07:35:13

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:34:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T02:35:06', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '960a4424-f519-46e8-8536-c0079b5caad9'	System	20 Aug 2020 07:35:13
User entered '97.4'	System	20 Aug 2020 07:35:13

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T02:35:09', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '960a4424-f519-46e8-8536-c0079b5caad9'	System	20 Aug 2020 07:35:13
User entered 'No (N)'	System	20 Aug 2020 07:35:13

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:34:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T02:35:12', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '960a4424-f519-46e8-8536-c0079b5caad9' User entered '20 Aug 2020 02:35'	System	20 Aug 2020 07:35:13
	System	20 Aug 2020 07:35:13

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:34:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:34:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 17:26:31
User entered 'Day 7'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:34:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T23:38:19', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '32dc5965-4eb3-4393-890d-d72f57514ce4'	System	21 Aug 2020 04:38:37
User entered 'Yes (Y)'	System	21 Aug 2020 04:38:37

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:34:01

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T23:38:27', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '32dc5965-4eb3-4393-890d-d72f57514ce4'	System	21 Aug 2020 04:38:37
User entered '97.1'	System	21 Aug 2020 04:38:37

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T23:38:31', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '32dc5965-4eb3-4393-890d-d72f57514ce4'	System	21 Aug 2020 04:38:37
User entered 'No (N)'	System	21 Aug 2020 04:38:37

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:34:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T23:38:34', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '32dc5965-4eb3-4393-890d-d72f57514ce4'	System	21 Aug 2020 04:38:37
User entered '20 Aug 2020 23:38'	System	21 Aug 2020 04:38:37

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:34:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:34:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 17:26:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:34:01

[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 (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-14T13:04:55', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '57eb1508-6e29-4f71-a6d9-b0b75dd1353c'	System	14 Aug 2020 18:05:37
User entered 'None (1)'	System	14 Aug 2020 18:05:37

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:34:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-14T13:04:58', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '57eb1508-6e29-4f71-a6d9-b0b75dd1353c'	System	14 Aug 2020 18:05:37
User entered 'Yes (Y)'	System	14 Aug 2020 18:05:37

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:34:01

Please record - REDNESS AT INJECTION SITE (in mm)

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-14T13:05:05', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '57eb1508-6e29-4f71-a6d9-b0b75dd1353c' User entered '10'	System	14 Aug 2020 18:05:37
	System	14 Aug 2020 18:05:37

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-14T13:05:08', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '57eb1508-6e29-4f71-a6d9-b0b75dd1353c'	System	14 Aug 2020 18:05:37
User entered 'No (N)'	System	14 Aug 2020 18:05:37

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:34:01

[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 (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-14T13:05:31', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '57eb1508-6e29-4f71-a6d9-b0b75dd1353c'	System	14 Aug 2020 18:05:37
User entered 'None (1)'	System	14 Aug 2020 18:05:37

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:34:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-14T13:05:34', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '57eb1508-6e29-4f71-a6d9-b0b75dd1353c'	System	14 Aug 2020 18:05:37
User entered '14 Aug 2020 13:05'	System	14 Aug 2020 18:05:37

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:34:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:43'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:34:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 15:13'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 17:26:31
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:34:01

[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 (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-15T10:44:29', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'd79db794-cac9-44ff-8ff5-ef28a097b2bc'	System	15 Aug 2020 15:54:36
User entered 'Does not interfere with activity (2)'	System	15 Aug 2020 15:54:36

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-15T10:52:33', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'd79db794-cac9-44ff-8ff5-ef28a097b2bc'	System	15 Aug 2020 15:54:36
User entered 'No (N)'	System	15 Aug 2020 15:54:36

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-15T10:53:30', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'd79db794-cac9-44ff-8ff5-ef28a097b2bc'	System	15 Aug 2020 15:54:36
User entered 'No (N)'	System	15 Aug 2020 15:54:36

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:34:01

[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 (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-15T10:54:27', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'd79db794-cac9-44ff-8ff5-ef28a097b2bc'	System	15 Aug 2020 15:54:36
User entered 'None (1)'	System	15 Aug 2020 15:54:36

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:34:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-15T10:54:32', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'd79db794-cac9-44ff-8ff5-ef28a097b2bc'	System	15 Aug 2020 15:54:36
User entered '15 Aug 2020 10:54'	System	15 Aug 2020 15:54:36

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:34:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 16:08'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:34:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 17:26:31
User entered 'Day 2'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:34:01

[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 (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T00:23:30', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'c4b65e8b-1eab-4da6-9556-f3c4e987d2a6'	System	16 Aug 2020 05:25:07
User entered 'Does not interfere with activity (2)'	System	16 Aug 2020 05:25:07

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:34:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T00:23:33', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'c4b65e8b-1eab-4da6-9556-f3c4e987d2a6'	System	16 Aug 2020 05:25:07
User entered 'No (N)'	System	16 Aug 2020 05:25:07

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T00:23:38', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'c4b65e8b-1eab-4da6-9556-f3c4e987d2a6'	System	16 Aug 2020 05:25:07
User entered 'No (N)'	System	16 Aug 2020 05:25:07

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:34:01

[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 (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T00:25:02', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'c4b65e8b-1eab-4da6-9556-f3c4e987d2a6'	System	16 Aug 2020 05:25:07
User entered 'None (1)'	System	16 Aug 2020 05:25:07

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:34:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T00:25:05', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'c4b65e8b-1eab-4da6-9556-f3c4e987d2a6'	System	16 Aug 2020 05:25:07
User entered '16 Aug 2020 00:25'	System	16 Aug 2020 05:25:07

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:34:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:34:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 17:26:31
User entered 'Day 3'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:34:01

[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 (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T22:43:13', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '8b6b1fa9-b293-40df-a865-75fb5d6a4aaa'	System	17 Aug 2020 03:43:37
User entered 'Does not interfere with activity (2)'	System	17 Aug 2020 03:43:37

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:34:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T22:43:16', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '8b6b1fa9-b293-40df-a865-75fb5d6a4aaa'	System	17 Aug 2020 03:43:37
User entered 'No (N)'	System	17 Aug 2020 03:43:37

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T22:43:19', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '8b6b1fa9-b293-40df-a865-75fb5d6a4aaa'	System	17 Aug 2020 03:43:37
User entered 'No (N)'	System	17 Aug 2020 03:43:37

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:34:01

[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 (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T22:43:31', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '8b6b1fa9-b293-40df-a865-75fb5d6a4aaa'	System	17 Aug 2020 03:43:37
User entered 'None (1)'	System	17 Aug 2020 03:43:37

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:34:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T22:43:34', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '8b6b1fa9-b293-40df-a865-75fb5d6a4aaa'	System	17 Aug 2020 03:43:37
User entered '16 Aug 2020 22:43'	System	17 Aug 2020 03:43:37

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:34:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:34:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 17:26:31
User entered 'Day 4'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:34:01

[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 (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-18T02:13:00', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'f3b655ed-883a-481b-9f37-4af45581fd4f'	System	18 Aug 2020 07:13:16
User entered 'None (1)'	System	18 Aug 2020 07:13:16

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:34:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-18T02:13:04', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'f3b655ed-883a-481b-9f37-4af45581fd4f'	System	18 Aug 2020 07:13:16
User entered 'No (N)'	System	18 Aug 2020 07:13:16

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-18T02:13:07', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'f3b655ed-883a-481b-9f37-4af45581fd4f'	System	18 Aug 2020 07:13:16
User entered 'No (N)'	System	18 Aug 2020 07:13:16

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:34:01

[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 (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-18T02:13:11', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'f3b655ed-883a-481b-9f37-4af45581fd4f'	System	18 Aug 2020 07:13:16
User entered 'None (1)'	System	18 Aug 2020 07:13:16

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:34:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-18T02:13:14', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'f3b655ed-883a-481b-9f37-4af45581fd4f'	System	18 Aug 2020 07:13:16
User entered '18 Aug 2020 02:13'	System	18 Aug 2020 07:13:16

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:34:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:34:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 17:26:31
User entered 'Day 5'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:34:01

[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 (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-19T00:56:00', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'ca6be480-45c0-4735-b66d-6699e8079ecc'	System	19 Aug 2020 05:56:14
User entered 'None (1)'	System	19 Aug 2020 05:56:14

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:34:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-19T00:56:03', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'ca6be480-45c0-4735-b66d-6699e8079ecc'	System	19 Aug 2020 05:56:14
User entered 'No (N)'	System	19 Aug 2020 05:56:14

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-19T00:56:06', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'ca6be480-45c0-4735-b66d-6699e8079ecc'	System	19 Aug 2020 05:56:14
User entered 'No (N)'	System	19 Aug 2020 05:56:14

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:34:01

[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 (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-19T00:56:08', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'ca6be480-45c0-4735-b66d-6699e8079ecc'	System	19 Aug 2020 05:56:14
User entered 'None (1)'	System	19 Aug 2020 05:56:14

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:34:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-19T00:56:10', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'ca6be480-45c0-4735-b66d-6699e8079ecc'	System	19 Aug 2020 05:56:14
User entered '19 Aug 2020 00:56'	System	19 Aug 2020 05:56:14

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:34:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:34:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 17:26:31
User entered 'Day 6'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:34:01

[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 (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T02:35:16', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'feb9da16-e431-4f0f-a57a-92401547da56'	System	20 Aug 2020 07:35:28
User entered 'None (1)'	System	20 Aug 2020 07:35:28

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:34:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T02:35:18', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'feb9da16-e431-4f0f-a57a-92401547da56'	System	20 Aug 2020 07:35:28
User entered 'No (N)'	System	20 Aug 2020 07:35:28

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T02:35:20', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'feb9da16-e431-4f0f-a57a-92401547da56'	System	20 Aug 2020 07:35:28
User entered 'No (N)'	System	20 Aug 2020 07:35:28

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:34:01

[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 (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T02:35:22', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'feb9da16-e431-4f0f-a57a-92401547da56'	System	20 Aug 2020 07:35:28
User entered 'None (1)'	System	20 Aug 2020 07:35:28

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:34:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T02:35:25', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'feb9da16-e431-4f0f-a57a-92401547da56'	System	20 Aug 2020 07:35:28
User entered '20 Aug 2020 02:35'	System	20 Aug 2020 07:35:28

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:34:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:34:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 17:26:31
User entered 'Day 7'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:34:01

[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 (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T23:38:38', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'f4a32446-47e2-4974-bcdc-f843e150288c'	System	21 Aug 2020 04:38:52
User entered 'None (1)'	System	21 Aug 2020 04:38:52

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T23:38:41', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'f4a32446-47e2-4974-bcdc-f843e150288c'	System	21 Aug 2020 04:38:52
User entered 'No (N)'	System	21 Aug 2020 04:38:52

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T23:38:44', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'f4a32446-47e2-4974-bcdc-f843e150288c'	System	21 Aug 2020 04:38:52
User entered 'No (N)'	System	21 Aug 2020 04:38:52

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:34:01

[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 (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T23:38:46', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'f4a32446-47e2-4974-bcdc-f843e150288c'	System	21 Aug 2020 04:38:52
User entered 'None (1)'	System	21 Aug 2020 04:38:52

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:34:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T23:38:48', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'f4a32446-47e2-4974-bcdc-f843e150288c'	System	21 Aug 2020 04:38:52
User entered '20 Aug 2020 23:38'	System	21 Aug 2020 04:38:52

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:34:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:34:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 17:26:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:34:01

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-14T13:06:06', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '0a9a0909-d0fb-44e3-9cff-96c679da0b96'	System	14 Aug 2020 18:06:47
User entered 'No interference with activity (1)'	System	14 Aug 2020 18:06:47

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:34:01

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-14T13:06:11', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '0a9a0909-d0fb-44e3-9cff-96c679da0b96'	System	14 Aug 2020 18:06:47
User entered 'None (0)'	System	14 Aug 2020 18:06:47

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:34:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-14T13:06:16', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '0a9a0909-d0fb-44e3-9cff-96c679da0b96'	System	14 Aug 2020 18:06:47
User entered 'None (0)'	System	14 Aug 2020 18:06:47

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:34:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-14T13:06:19', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '0a9a0909-d0fb-44e3-9cff-96c679da0b96'	System	14 Aug 2020 18:06:47
User entered 'None (0)'	System	14 Aug 2020 18:06:47

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:34:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-14T13:06:27', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '0a9a0909-d0fb-44e3-9cff-96c679da0b96'	System	14 Aug 2020 18:06:47
User entered 'None (0)'	System	14 Aug 2020 18:06:47

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:34:01

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-14T13:06:31', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '0a9a0909-d0fb-44e3-9cff-96c679da0b96'	System	14 Aug 2020 18:06:47
User entered 'None (0)'	System	14 Aug 2020 18:06:47

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:34:01

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 (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-14T13:06:41', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '0a9a0909-d0fb-44e3-9cff-96c679da0b96'	System	14 Aug 2020 18:06:47
User entered 'No (N)'	System	14 Aug 2020 18:06:47

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:34:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-14T13:06:44', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '0a9a0909-d0fb-44e3-9cff-96c679da0b96'	System	14 Aug 2020 18:06:47
User entered '14 Aug 2020 13:06'	System	14 Aug 2020 18:06:47

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:34:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:43'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:34:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 15:13'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 17:26:31
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:34:01

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-15T10:54:42', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '8d8b431d-37ad-4e3d-9df7-d324816667c6'	System	15 Aug 2020 15:55:46
User entered 'No interference with activity (1)'	System	15 Aug 2020 15:55:46

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:34:01

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-15T10:54:51', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '8d8b431d-37ad-4e3d-9df7-d324816667c6'	System	15 Aug 2020 15:55:46
User entered 'None (0)'	System	15 Aug 2020 15:55:46

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:34:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-15T10:55:03', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '8d8b431d-37ad-4e3d-9df7-d324816667c6'	System	15 Aug 2020 15:55:46
User entered 'None (0)'	System	15 Aug 2020 15:55:46

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:34:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-15T10:55:25', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '8d8b431d-37ad-4e3d-9df7-d324816667c6'	System	15 Aug 2020 15:55:46
User entered 'None (0)'	System	15 Aug 2020 15:55:46

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:34:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-15T10:55:32', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '8d8b431d-37ad-4e3d-9df7-d324816667c6'	System	15 Aug 2020 15:55:46
User entered 'None (0)'	System	15 Aug 2020 15:55:46

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:34:01

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-15T10:55:35', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '8d8b431d-37ad-4e3d-9df7-d324816667c6'	System	15 Aug 2020 15:55:46
User entered 'None (0)'	System	15 Aug 2020 15:55:46

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:34:01

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 (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-15T10:55:41', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '8d8b431d-37ad-4e3d-9df7-d324816667c6'	System	15 Aug 2020 15:55:46
User entered 'No (N)'	System	15 Aug 2020 15:55:46

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:34:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-15T10:55:44', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '8d8b431d-37ad-4e3d-9df7-d324816667c6'	System	15 Aug 2020 15:55:46
User entered '15 Aug 2020 10:55'	System	15 Aug 2020 15:55:46

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:34:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 16:08'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:34:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 17:26:31
User entered 'Day 2'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:34:01

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T00:25:18', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '5ec4978e-ee56-40d0-8173-5e3a5e96aa41'	System	16 Aug 2020 05:26:04
User entered 'No interference with activity (1)'	System	16 Aug 2020 05:26:04

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:34:01

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T00:25:29', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '5ec4978e-ee56-40d0-8173-5e3a5e96aa41'	System	16 Aug 2020 05:26:04
User entered 'No interference with activity (1)'	System	16 Aug 2020 05:26:04

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:34:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T00:25:34', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '5ec4978e-ee56-40d0-8173-5e3a5e96aa41' User entered 'None (0)'	System	16 Aug 2020 05:26:04
	System	16 Aug 2020 05:26:04

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:34:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T00:25:50', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '5ec4978e-ee56-40d0-8173-5e3a5e96aa41'	System	16 Aug 2020 05:26:04
User entered 'No interference with activity (1)'	System	16 Aug 2020 05:26:04

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:34:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T00:25:53', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '5ec4978e-ee56-40d0-8173-5e3a5e96aa41'	System	16 Aug 2020 05:26:04
User entered 'None (0)'	System	16 Aug 2020 05:26:04

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:34:01

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T00:25:56', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '5ec4978e-ee56-40d0-8173-5e3a5e96aa41'	System	16 Aug 2020 05:26:04
User entered 'None (0)'	System	16 Aug 2020 05:26:04

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:34:01

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 (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T00:26:00', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '5ec4978e-ee56-40d0-8173-5e3a5e96aa41'	System	16 Aug 2020 05:26:04
User entered 'No (N)'	System	16 Aug 2020 05:26:04

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:34:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T00:26:03', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '5ec4978e-ee56-40d0-8173-5e3a5e96aa41'	System	16 Aug 2020 05:26:04
User entered '16 Aug 2020 00:26'	System	16 Aug 2020 05:26:04

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:34:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:34:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:34:01

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 17:26:31
User entered 'Day 3'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:34:01

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T22:43:38', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '46761bad-7704-4e60-9f9c-d7777d8047d7'	System	17 Aug 2020 03:43:59
User entered 'None (0)'	System	17 Aug 2020 03:43:59

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:34:01

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T22:43:41', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '46761bad-7704-4e60-9f9c-d7777d8047d7'	System	17 Aug 2020 03:43:59
User entered 'None (0)'	System	17 Aug 2020 03:43:59

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:34:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T22:43:44', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '46761bad-7704-4e60-9f9c-d7777d8047d7'	System	17 Aug 2020 03:43:59
User entered 'None (0)'	System	17 Aug 2020 03:43:59

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:34:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T22:43:46', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '46761bad-7704-4e60-9f9c-d7777d8047d7'	System	17 Aug 2020 03:43:59
User entered 'None (0)'	System	17 Aug 2020 03:43:59

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:34:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T22:43:48', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '46761bad-7704-4e60-9f9c-d7777d8047d7'	System	17 Aug 2020 03:43:59
User entered 'None (0)'	System	17 Aug 2020 03:43:59

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:34:01

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T22:43:50', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '46761bad-7704-4e60-9f9c-d7777d8047d7'	System	17 Aug 2020 03:43:59
User entered 'None (0)'	System	17 Aug 2020 03:43:59

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:34:01

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 (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T22:43:53', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '46761bad-7704-4e60-9f9c-d7777d8047d7'	System	17 Aug 2020 03:43:59
User entered 'No (N)'	System	17 Aug 2020 03:43:59

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:34:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T22:43:55', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '46761bad-7704-4e60-9f9c-d7777d8047d7'	System	17 Aug 2020 03:43:59
User entered '16 Aug 2020 22:43'	System	17 Aug 2020 03:43:59

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:34:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:34:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 17:26:31
User entered 'Day 4'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:34:01

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-18T02:13:22', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'e4c33fbb-d9b5-49ba-9a70-7061fa12ba98'	System	18 Aug 2020 07:13:53
User entered 'None (0)'	System	18 Aug 2020 07:13:53

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:34:01

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-18T02:13:25', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'e4c33fbb-d9b5-49ba-9a70-7061fa12ba98'	System	18 Aug 2020 07:13:53
User entered 'None (0)'	System	18 Aug 2020 07:13:53

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:34:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-18T02:13:28', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'e4c33fbb-d9b5-49ba-9a70-7061fa12ba98'	System	18 Aug 2020 07:13:53
User entered 'None (0)'	System	18 Aug 2020 07:13:53

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:34:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-18T02:13:32', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'e4c33fbb-d9b5-49ba-9a70-7061fa12ba98'	System	18 Aug 2020 07:13:53
User entered 'None (0)'	System	18 Aug 2020 07:13:53

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:34:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-18T02:13:34', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'e4c33fbb-d9b5-49ba-9a70-7061fa12ba98'	System	18 Aug 2020 07:13:53
User entered 'None (0)'	System	18 Aug 2020 07:13:53

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:34:01

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-18T02:13:42', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'e4c33fbb-d9b5-49ba-9a70-7061fa12ba98'	System	18 Aug 2020 07:13:53
User entered 'None (0)'	System	18 Aug 2020 07:13:53

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:34:01

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 (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-18T02:13:48', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'e4c33fbb-d9b5-49ba-9a70-7061fa12ba98'	System	18 Aug 2020 07:13:53
User entered 'No (N)'	System	18 Aug 2020 07:13:53

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:34:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-18T02:13:51', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'e4c33fbb-d9b5-49ba-9a70-7061fa12ba98'	System	18 Aug 2020 07:13:53
User entered '18 Aug 2020 02:13'	System	18 Aug 2020 07:13:53

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:34:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:34:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:34:01

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 17:26:31
User entered 'Day 5'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:34:01

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-19T00:56:15', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'ce8f3f4d-61d5-4ca8-a4fe-f8885ca3fe15'	System	19 Aug 2020 05:56:35
User entered 'None (0)'	System	19 Aug 2020 05:56:35

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:34:01

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-19T00:56:17', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'ce8f3f4d-61d5-4ca8-a4fe-f8885ca3fe15'	System	19 Aug 2020 05:56:35
User entered 'None (0)'	System	19 Aug 2020 05:56:35

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:34:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-19T00:56:21', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'ce8f3f4d-61d5-4ca8-a4fe-f8885ca3fe15'	System	19 Aug 2020 05:56:35
User entered 'None (0)'	System	19 Aug 2020 05:56:35

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:34:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-19T00:56:24', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'ce8f3f4d-61d5-4ca8-a4fe-f8885ca3fe15'	System	19 Aug 2020 05:56:35
User entered 'None (0)'	System	19 Aug 2020 05:56:35

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:34:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-19T00:56:26', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'ce8f3f4d-61d5-4ca8-a4fe-f8885ca3fe15'	System	19 Aug 2020 05:56:35
User entered 'None (0)'	System	19 Aug 2020 05:56:35

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:34:01

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-19T00:56:28', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'ce8f3f4d-61d5-4ca8-a4fe-f8885ca3fe15'	System	19 Aug 2020 05:56:35
User entered 'None (0)'	System	19 Aug 2020 05:56:35

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:34:01

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 (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-19T00:56:31', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'ce8f3f4d-61d5-4ca8-a4fe-f8885ca3fe15'	System	19 Aug 2020 05:56:35
User entered 'No (N)'	System	19 Aug 2020 05:56:35

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:34:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-19T00:56:33', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'ce8f3f4d-61d5-4ca8-a4fe-f8885ca3fe15'	System	19 Aug 2020 05:56:35
User entered '19 Aug 2020 00:56'	System	19 Aug 2020 05:56:35

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:34:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:34:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 17:26:31
User entered 'Day 6'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:34:01

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T02:35:32', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'f56ebfb8-43ee-4ab1-ab54-866e6b4bbe85'	System	20 Aug 2020 07:35:46
User entered 'None (0)'	System	20 Aug 2020 07:35:46

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:34:01

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T02:35:34', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'f56ebfb8-43ee-4ab1-ab54-866e6b4bbe85'	System	20 Aug 2020 07:35:46
User entered 'None (0)'	System	20 Aug 2020 07:35:46

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:34:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T02:35:35', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'f56ebfb8-43ee-4ab1-ab54-866e6b4bbe85'	System	20 Aug 2020 07:35:46
User entered 'None (0)'	System	20 Aug 2020 07:35:46

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:34:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T02:35:37', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'f56ebfb8-43ee-4ab1-ab54-866e6b4bbe85'	System	20 Aug 2020 07:35:46
User entered 'None (0)'	System	20 Aug 2020 07:35:46

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:34:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T02:35:39', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'f56ebfb8-43ee-4ab1-ab54-866e6b4bbe85'	System	20 Aug 2020 07:35:46
User entered 'None (0)'	System	20 Aug 2020 07:35:46

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:34:01

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T02:35:40', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'f56ebfb8-43ee-4ab1-ab54-866e6b4bbe85'	System	20 Aug 2020 07:35:46
User entered 'None (0)'	System	20 Aug 2020 07:35:46

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:34:01

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 (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T02:35:42', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'f56ebfb8-43ee-4ab1-ab54-866e6b4bbe85'	System	20 Aug 2020 07:35:46
User entered 'No (N)'	System	20 Aug 2020 07:35:46

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:34:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T02:35:44', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'f56ebfb8-43ee-4ab1-ab54-866e6b4bbe85'	System	20 Aug 2020 07:35:46
User entered '20 Aug 2020 02:35'	System	20 Aug 2020 07:35:46

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:34:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:34:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 17:26:31
User entered 'Day 7'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:34:01

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T23:38:52', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'ceacd112-2c29-40cb-8d14-624125e0bf4c'	System	21 Aug 2020 04:39:16
User entered 'None (0)'	System	21 Aug 2020 04:39:16

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:34:01

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T23:38:55', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'ceacd112-2c29-40cb-8d14-624125e0bf4c'	System	21 Aug 2020 04:39:16
User entered 'None (0)'	System	21 Aug 2020 04:39:16

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:34:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T23:38:58', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'ceacd112-2c29-40cb-8d14-624125e0bf4c'	System	21 Aug 2020 04:39:16
User entered 'None (0)'	System	21 Aug 2020 04:39:16

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:34:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T23:39:02', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'ceacd112-2c29-40cb-8d14-624125e0bf4c'	System	21 Aug 2020 04:39:16
User entered 'None (0)'	System	21 Aug 2020 04:39:16

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:34:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T23:39:06', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'ceacd112-2c29-40cb-8d14-624125e0bf4c'	System	21 Aug 2020 04:39:16
User entered 'None (0)'	System	21 Aug 2020 04:39:16

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:34:01

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T23:39:08', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'ceacd112-2c29-40cb-8d14-624125e0bf4c'	System	21 Aug 2020 04:39:16
User entered 'None (0)'	System	21 Aug 2020 04:39:16

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:34:01

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 (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T23:39:11', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'ceacd112-2c29-40cb-8d14-624125e0bf4c'	System	21 Aug 2020 04:39:16
User entered 'No (N)'	System	21 Aug 2020 04:39:16

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:34:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T23:39:13', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'ceacd112-2c29-40cb-8d14-624125e0bf4c'	System	21 Aug 2020 04:39:16
User entered '20 Aug 2020 23:39'	System	21 Aug 2020 04:39:16

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:34:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 17:26:31

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:34:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 17:26:31

US3552035

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 17:01:36
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	21 Aug 2020 20:35:53

US3552035

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:01

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 17:01:36
User entered '21 Aug 2020'	Mikayla Frye (b) (4) (b) (4)	21 Aug 2020 20:35:53

US3552035

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 17:01:36
User entered 'Contact Made (CONTACT MADE)'	Mikayla Frye (b) (4) (b) (4)	21 Aug 2020 20:35:53

US3552035

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 17:01:36
User entered empty.	Mikayla Frye (b) (4) (b) (4)	21 Aug 2020 20:35:53

US3552035

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 17:01:41
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 15:40:44

US3552035

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Aug 2020 15:40:44

US3552035

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:48:53
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 15:40:52

US3552035

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:01

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:48:53
User entered '29 Aug 2020'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 15:40:52

US3552035

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:48:53
User entered 'Contact Made (CONTACT MADE)'	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 15:40:52

US3552035

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:48:53
User entered empty.	Mikayla Frye (b) (4) (b) (4)	29 Aug 2020 15:40:52

US3552035

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:48:59
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	04 Sep 2020 21:17:24

US3552035

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 21:17:24

US3552035

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:50:20
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	04 Sep 2020 21:17:31

US3552035

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:01

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:33:21
DataPoint Un-verified.	Stanley Doublin (b) (4)	09 Nov 2020 19:02:53
User entered '04 Sep 2020' reason for change: Data Entry Error	Stanley Doublin (b) (4)	09 Nov 2020 19:02:53
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:50:20
User entered '4 Sep 2020'	Mikayla Frye (b) (4)	04 Sep 2020 21:17:31

US3552035

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:50:20
User entered 'Contact Made (CONTACT MADE)'	Mikayla Frye (b) (4) (b) (4)	04 Sep 2020 21:17:31

US3552035

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:50:20
User entered empty.	Mikayla Frye (b) (4) (b) (4)	04 Sep 2020 21:17:31

US3552035

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:33:28
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	22 Sep 2020 18:34:43

US3552035

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 18:34:43

US3552035

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:34:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:34:22
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	22 Sep 2020 18:34:53

US3552035

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:34:22
User entered '17 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	22 Sep 2020 18:34:53

US3552035

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:34:22
User entered 'Clinic (Clinic)'	Stanley Doublin (b) (4) (b) (4)	22 Sep 2020 18:34:53

US3552035

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:34:01

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	22 Sep 2020 18:34:53

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:01

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 18:35:21

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:13:54
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	22 Sep 2020 18:35:21

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:13:54
User entered '17 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	22 Sep 2020 18:35:21

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:13:54
User entered '12:45'	Stanley Doublin (b) (4) (b) (4)	22 Sep 2020 18:35:21

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:45'	System	22 Sep 2020 18:35:21

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:13:54
User entered '97.7' F	Stanley Doublin (b) (4) (b) (4)	22 Sep 2020 18:35:21

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:01

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:13:54
User entered 'Oral (Oral)'	Stanley Doublin (b) (4) (b) (4)	22 Sep 2020 18:35:21

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:01

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:13:54
User entered empty.	Stanley Doublin (b) (4) (b) (4)	22 Sep 2020 18:35:21

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:13:54
User entered '66'	Stanley Doublin (b) (4) (b) (4)	22 Sep 2020 18:35:21

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:01

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	22 Sep 2020 18:35:21

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:13:54
User entered '16'	Stanley Doublin (b) (4) (b) (4)	22 Sep 2020 18:35:21

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	22 Sep 2020 18:35:21

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:13:54
User entered '120'	Stanley Doublin (b) (4) (b) (4)	22 Sep 2020 18:35:21

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	22 Sep 2020 18:35:21

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:13:54
User entered '74'	Stanley Doublin (b) (4) (b) (4)	22 Sep 2020 18:35:21

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:34:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	22 Sep 2020 18:35:21

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:01

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Stanley Dublin (b) (4) (b) (4)	22 Sep 2020 18:35:28

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:13:54
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	22 Sep 2020 18:35:28

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:13:54
User entered empty.	Stanley Doublin (b) (4) (b) (4)	22 Sep 2020 18:35:28

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:13:54
User entered empty.	Stanley Doublin (b) (4) (b) (4)	22 Sep 2020 18:35:28

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 18:35:28

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:13:54
User entered empty.	Stanley Doublin (b) (4) (b) (4)	22 Sep 2020 18:35:28

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:01

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:13:54
User entered empty.	Stanley Doublin (b) (4) (b) (4)	22 Sep 2020 18:35:28

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:01

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:13:54
User entered empty.	Stanley Doublin (b) (4) (b) (4)	22 Sep 2020 18:35:28

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:13:54
User entered empty.	Stanley Doublin (b) (4) (b) (4)	22 Sep 2020 18:35:28

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:01

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 18:35:28

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:13:54
User entered empty.	Stanley Doublin (b) (4) (b) (4)	22 Sep 2020 18:35:28

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 18:35:28

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:13:54
User entered empty.	Stanley Doublin (b) (4) (b) (4)	22 Sep 2020 18:35:28

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 18:35:28

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:13:54
User entered empty.	Stanley Doublin (b) (4) (b) (4)	22 Sep 2020 18:35:28

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:34:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 18:35:28

US3552035

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:34:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:14:18
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	22 Sep 2020 18:35:45

US3552035

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:14:18
User entered '17 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	22 Sep 2020 18:35:45

US3552035

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:34:01

[Was study treatment given?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:14:22
User closed query 'Was study treatment given? Is No but any of these is present: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	22 Sep 2020 18:38:51
Query 'Was study treatment given? Is No but any of these is present: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' answered by data change (Site from System).	System	22 Sep 2020 18:38:51
User opened query 'Was study treatment given? Is No but any of these is present: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	22 Sep 2020 18:38:26
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	22 Sep 2020 18:38:26

US3552035

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:34:01

[If No, reason not given](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:14:22
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)'	Stanley Doublin (b) (4) (b) (4)	22 Sep 2020 18:38:26

US3552035

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:14:22
User closed query 'Please add AE term (Shingles Infection)' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 17:05:32
Query 'Please add AE term (Shingles Infection)' answered with 'done' (Site from CRA).	Cassandra Zehenny (b) (4)	18 Nov 2020 16:16:12
User entered 'shingles infection' reason for change: Per Query Resolution	(b) (4)	18 Nov 2020 16:15:41
User opened query 'Please add AE term (Shingles Infection)' (Site from CRA).	Cassandra Zehenny (b) (4)	18 Nov 2020 02:26:35
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 18:38:26
	Stanley Doublin (b) (4)	
	(b) (4)	

US3552035

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:34:01

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 18:38:26

US3552035

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:14:22
User entered empty; reason for change Data Entry Error	Stanley Doublin (b) (4)	22 Sep 2020 18:38:51
User entered '17 Sep 2020'	Stanley Doublin (b) (4)	22 Sep 2020 18:38:26

US3552035

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:14:22
User entered empty.	Stanley Doublin (b) (4) (b) (4)	22 Sep 2020 18:38:26

US3552035

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 18:38:26

US3552035

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:14:22
User entered empty.	Stanley Doublin (b) (4) (b) (4)	22 Sep 2020 18:38:26

US3552035

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:14:22
User entered empty.	System	22 Sep 2020 18:38:26

US3552035

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 18:38:26

US3552035

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:34:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:14:28
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	22 Sep 2020 18:39:04

US3552035

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:34:01

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:14:28
Query 'Per IMMUNO Lab Recon: it appears a sample was collected on 17SEP2020; however, it has not been received by GCL. Please clarify and, if shipped, please provide tracking details.' answered with 'No open lab queries, please speak with GCL' (Site from DM).	Heather Douds (b) (4) (b) (4)	08 Oct 2020 15:37:43
User opened query 'Per IMMUNO Lab Recon: it appears a sample was collected on 17SEP2020; however, it has not been received by GCL. Please clarify and, if shipped, please provide tracking details.' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 09:24:46
User entered '17 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	22 Sep 2020 18:39:04

US3552035

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:14:28
User entered '13:11'	Stanley Doublin (b) (4) (b) (4)	22 Sep 2020 18:39:04

US3552035

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
User entered '17 Sep 2020 13:11'	System	22 Sep 2020 18:39:04

US3552035

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:16:24
User entered '17 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	22 Sep 2020 18:39:17

US3552035

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:34:01

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Stanley Dublin (b) (4)	22 Sep 2020 18:39:17

US3552035

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:34:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:16:24
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	22 Sep 2020 18:39:17

US3552035

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:16:24
User entered '13:14'	Stanley Doublin (b) (4) (b) (4)	22 Sep 2020 18:39:17

US3552035

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
User entered '17 Sep 2020 13:14'	System	22 Sep 2020 18:39:17

US3552035

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:34:01

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Stanley Dublin (b) (4)	22 Sep 2020 18:39:17

US3552035

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:34:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:16:24
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	22 Sep 2020 18:39:17

US3552035

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:16:24
User entered empty.	Stanley Doublin (b) (4) (b) (4)	22 Sep 2020 18:39:17

US3552035

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 18:39:17

US3552035

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:05:10
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	24 Sep 2020 17:12:25

US3552035

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Sep 2020 17:12:25

US3552035

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:05:18
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	24 Sep 2020 17:12:37

US3552035

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:01

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:05:18
User entered '24 Sep 2020'	Stanley Doublin (b) (4) (b) (4)	24 Sep 2020 17:12:37

US3552035

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:05:18
User entered 'Contact Made (CONTACT MADE)'	Stanley Doublin (b) (4) (b) (4)	24 Sep 2020 17:12:37

US3552035

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:05:18
User entered empty.	Stanley Doublin (b) (4) (b) (4)	24 Sep 2020 17:12:37

US3552035

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:05:26
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	01 Oct 2020 16:51:07

US3552035

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 16:51:07

US3552035

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:16:46
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	01 Oct 2020 16:51:15

US3552035

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:01

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:16:46
User entered '01 Oct 2020' reason for change: Data Entry Error	Stanley Doublin (b) (4)	09 Nov 2020 19:03:14
User entered '1 Oct 2020'	Stanley Doublin (b) (4)	01 Oct 2020 16:51:15

US3552035

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:16:46
User entered 'Contact Made (CONTACT MADE)'	Stanley Doublin (b) (4) (b) (4)	01 Oct 2020 16:51:15

US3552035

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:16:46
User entered empty.	Stanley Doublin (b) (4) (b) (4)	01 Oct 2020 16:51:15

US3552035

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:16:51
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	08 Oct 2020 19:20:45

US3552035

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Oct 2020 19:20:45

US3552035

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:16:56
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	08 Oct 2020 19:20:55

US3552035

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:01

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:16:56
User entered '08 Oct 2020' reason for change: Data Entry Error	Stanley Doublin (b) (4)	09 Nov 2020 19:03:24
User entered '8 Oct 2020'	Stanley Doublin (b) (4)	08 Oct 2020 19:20:55

US3552035

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:16:56
User entered 'Contact Made (CONTACT MADE)'	Stanley Doublin (b) (4) (b) (4)	08 Oct 2020 19:20:55

US3552035

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:16:56
User entered empty.	Stanley Doublin (b) (4) (b) (4)	08 Oct 2020 19:20:55

US3552035

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:17:02
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	12 Oct 2020 18:58:52

US3552035

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 18:58:52

US3552035

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:34:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:17:07
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	12 Oct 2020 18:59:15

US3552035

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:17:07
User entered '12 Oct 2020'	Stanley Doublin (b) (4) (b) (4)	12 Oct 2020 18:59:15

US3552035

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:17:07
User entered 'Clinic (Clinic)'	Stanley Doublin (b) (4) (b) (4)	12 Oct 2020 18:59:15

US3552035

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:34:01

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	12 Oct 2020 18:59:15

US3552035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:17:12
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	12 Oct 2020 18:59:29

US3552035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:17:12
User entered empty.	Stanley Doublin (b) (4) (b) (4)	12 Oct 2020 18:59:29

US3552035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:17:12
User entered empty.	Stanley Doublin (b) (4) (b) (4)	12 Oct 2020 18:59:29

US3552035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 18:59:29

US3552035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:17:12
User entered empty.	Stanley Doublin (b) (4) (b) (4)	12 Oct 2020 18:59:29

US3552035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:01

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:17:12
User entered empty.	Stanley Doublin (b) (4) (b) (4)	12 Oct 2020 18:59:29

US3552035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:01

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:17:12
User entered empty.	Stanley Doublin (b) (4) (b) (4)	12 Oct 2020 18:59:29

US3552035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:17:12
User entered empty.	Stanley Doublin (b) (4) (b) (4)	12 Oct 2020 18:59:29

US3552035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:01

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 18:59:29

US3552035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:17:12
User entered empty.	Stanley Doublin (b) (4) (b) (4)	12 Oct 2020 18:59:29

US3552035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 18:59:29

US3552035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:17:12
User entered empty.	Stanley Doublin (b) (4) (b) (4)	12 Oct 2020 18:59:29

US3552035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 18:59:29

US3552035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:17:12
User entered empty.	Stanley Doublin (b) (4) (b) (4)	12 Oct 2020 18:59:29

US3552035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:34:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 18:59:29

US3552035

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:34:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:17:18
User entered 'No (N)'	Stanley Doublin (b) (4) (b) (4)	12 Oct 2020 18:59:34

US3552035

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:17:18
User entered empty.	Stanley Doublin (b) (4) (b) (4)	12 Oct 2020 18:59:34

US3552035

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:34:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:17:22
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	12 Oct 2020 18:59:45

US3552035

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:17:22
User entered '12 Oct 2020'	Stanley Doublin (b) (4) (b) (4)	12 Oct 2020 18:59:45

US3552035

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:17:22
User entered '11:00'	Stanley Doublin (b) (4) (b) (4)	12 Oct 2020 18:59:45

US3552035

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
User entered '12 Oct 2020 11:00'	System	12 Oct 2020 18:59:45

US3552035

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:17:27
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	12 Nov 2020 20:01:59

US3552035

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:34:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 20:01:59

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 17:26:31
User entered 'Day 64'	System	14 Aug 2020 17:26:31

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[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 (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-10-14T00:50:24', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'c525c1af-077e-4cf4-bb6a-c1bb22972264'	System	14 Oct 2020 05:50:44
User entered 'No (N)'	System	14 Oct 2020 05:50:44

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

Have you been exposed to someone with 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 (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-10-14T00:50:30', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'c525c1af-077e-4cf4-bb6a-c1bb22972264'	System	14 Oct 2020 05:50:44
User entered 'No (N)'	System	14 Oct 2020 05:50:44

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-10-14T00:50:40', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'c525c1af-077e-4cf4-bb6a-c1bb22972264' User entered '14 Oct 2020 00:50:40'	System	14 Oct 2020 05:50:44
	System	14 Oct 2020 05:50:44

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 17:26:31
User entered '14 Oct 2020 00:01'	System	14 Aug 2020 17:26:31

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 17:26:31
User entered '18 Oct 2020 23:59'	System	14 Aug 2020 17:26:31

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 17:26:31
User entered 'Day 71'	System	14 Aug 2020 17:26:31

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-10-22T14:50:40', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'd6031b18-cf26-40c5-8e3c-be7c32160e6b' User entered 'No (N)'	System	22 Oct 2020 19:50:56
	System	22 Oct 2020 19:50:56

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

Have you been exposed to someone with 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 (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-10-22T14:50:43', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'd6031b18-cf26-40c5-8e3c-be7c32160e6b' User entered 'No (N)'	System	22 Oct 2020 19:50:56
	System	22 Oct 2020 19:50:56

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-10-22T14:50:50', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'd6031b18-cf26-40c5-8e3c-be7c32160e6b' User entered '22 Oct 2020 14:50:50'	System	22 Oct 2020 19:50:56
	System	22 Oct 2020 19:50:56

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 17:26:31
User entered '21 Oct 2020 00:01'	System	14 Aug 2020 17:26:31

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 17:26:31
User entered '25 Oct 2020 23:59'	System	14 Aug 2020 17:26:31

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 17:26:31
User entered 'Day 78'	System	14 Aug 2020 17:26:31

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-10-28T13:23:49', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'd108cae7-8a97-457c-8882-4cc63034c2f3'	System	28 Oct 2020 18:24:10
User entered 'No (N)'	System	28 Oct 2020 18:24:10

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

Have you been exposed to someone with 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 (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-10-28T13:23:55', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'd108cae7-8a97-457c-8882-4cc63034c2f3'	System	28 Oct 2020 18:24:10
User entered 'No (N)'	System	28 Oct 2020 18:24:10

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-10-28T13:24:00', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'd108cae7-8a97-457c-8882-4cc63034c2f3' User entered '28 Oct 2020 13:24:00'	System	28 Oct 2020 18:24:10
	System	28 Oct 2020 18:24:10

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 17:26:31
User entered '28 Oct 2020 00:01'	System	14 Aug 2020 17:26:31

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 17:26:31
User entered '01 Nov 2020 23:59'	System	14 Aug 2020 17:26:31

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 17:26:31
User entered 'Day 92'	System	14 Aug 2020 17:26:31

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-11-11T23:49:01', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'af82f553-0426-4762-85f1-765c5c9b872b'	System	12 Nov 2020 05:49:11
User entered 'No (N)'	System	12 Nov 2020 05:49:11

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

Have you been exposed to someone with 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 (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-11-11T23:49:05', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'af82f553-0426-4762-85f1-765c5c9b872b'	System	12 Nov 2020 05:49:11
User entered 'No (N)'	System	12 Nov 2020 05:49:11

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-11-11T23:49:08', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'af82f553-0426-4762-85f1-765c5c9b872b'	System	12 Nov 2020 05:49:11
User entered '11 Nov 2020 23:49:08'	System	12 Nov 2020 05:49:11

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 17:26:31
User entered '11 Nov 2020 00:01'	System	14 Aug 2020 17:26:31

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 17:26:31
User entered '15 Nov 2020 23:59'	System	14 Aug 2020 17:26:31

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 17:26:31
User entered 'Day 99'	System	14 Aug 2020 17:26:31

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

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 (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-11-18T00:01:16', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'ab657269-e6a3-4736-acca-8313f37c8dd1'	System	18 Nov 2020 06:01:29
User entered 'No (N)'	System	18 Nov 2020 06:01:29

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

Have you been exposed to someone with 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 (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-11-18T00:01:21', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'ab657269-e6a3-4736-acca-8313f37c8dd1'	System	18 Nov 2020 06:01:29
User entered 'No (N)'	System	18 Nov 2020 06:01:29

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-11-18T00:01:24', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'ab657269-e6a3-4736-acca-8313f37c8dd1' User entered '18 Nov 2020 00:01:24'	System	18 Nov 2020 06:01:29
	System	18 Nov 2020 06:01:29

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 17:26:31
User entered '18 Nov 2020 00:01'	System	14 Aug 2020 17:26:31

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	14 Aug 2020 17:26:31
User entered '22 Nov 2020 23:59'	System	14 Aug 2020 17:26:31

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '11 Oct 2020 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '15 Oct 2020 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '18 Oct 2020 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '22 Oct 2020 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '25 Oct 2020 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '29 Oct 2020 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '01 Nov 2020 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '05 Nov 2020 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '08 Nov 2020 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '12 Nov 2020 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '15 Nov 2020 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '19 Nov 2020 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[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 (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-11-23T02:02:25', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '4bd85ffd-928d-4df3-b2df-3fdb4e6f3b3b'	System	23 Nov 2020 08:02:43
User entered 'No (N)'	System	23 Nov 2020 08:02:43

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Have you been exposed to someone with 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 (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-11-23T02:02:33', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '4bd85ffd-928d-4df3-b2df-3fdb4e6f3b3b'	System	23 Nov 2020 08:02:43
User entered 'No (N)'	System	23 Nov 2020 08:02:43

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-11-23T02:02:36', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '4bd85ffd-928d-4df3-b2df-3fdb4e6f3b3b' User entered '23 Nov 2020 02:02:36'	System	23 Nov 2020 08:02:43
	System	23 Nov 2020 08:02:43

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '16 Oct 2022 00:01'	System	19 Nov 2020 07:35:44

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:34:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:35:44
Amendment Manager: User entered '20 Oct 2022 23:59'	System	19 Nov 2020 07:35:44

US3552035

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:17:33
User entered 'Yes (Y)'	Stanley Doublin (b) (4) (b) (4)	12 Nov 2020 20:02:08

US3552035

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:01

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:17:33
User entered '12 Nov 2020'	Stanley Doublin (b) (4) (b) (4)	12 Nov 2020 20:02:08

US3552035

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:17:33
User entered 'Contact Made (CONTACT MADE)'	Stanley Doublin (b) (4) (b) (4)	12 Nov 2020 20:02:08

US3552035

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:34:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:17:33
User entered empty.	Stanley Doublin (b) (4) (b) (4)	12 Nov 2020 20:02:08

US3552035

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:34:01

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 04:27:34
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	04 Sep 2020 21:22:27

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:01

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:22:48
User closed query 'Per DM CLR: Please specify the location if BILATERAL, LEFT, or RIGHT. 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)	05 Oct 2020 09:04:57
Query 'Per DM CLR: Please specify the location if BILATERAL, LEFT, or RIGHT. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' answered with 'data pending' (Site from DM).	Cassandra Zehenny (b) (4)	29 Sep 2020 18:59:48
User opened query 'Per DM CLR: Please specify the location if BILATERAL, LEFT, or RIGHT. 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)	29 Sep 2020 05:09:28
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Herpes zoster, LLT: Shingles - version MedDRA\23.0.	Coder Import (b) (4)	04 Sep 2020 21:25:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	04 Sep 2020 21:25:46
Data point term sent to Coder	System	04 Sep 2020 21:24:35
User entered 'shingles'	Mikayla Frye (b) (4)	04 Sep 2020 21:23:55

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:22:48
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	04 Sep 2020 21:23:55

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:22:48
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	04 Sep 2020 21:23:55

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:22:48
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	04 Sep 2020 21:23:55

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:22:48
User entered '04 Sep 2020' reason for change: Data Entry Error	Stanley Doublin (b) (4)	09 Nov 2020 19:03:55
User entered '4 Sep 2020'	Mikayla Frye (b) (4)	04 Sep 2020 21:23:55

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:22:48
User entered empty.	Mikayla Frye (b) (4) (b) (4)	04 Sep 2020 21:23:55

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:01

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 21:23:55

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:22:48
User entered 'No (N)' reason for change: Data Entry Error	Stanley Doublin (b) (4)	24 Sep 2020 17:11:59
User entered 'Yes (Y)'	Mikayla Frye (b) (4)	04 Sep 2020 21:23:55

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:01

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:22:48
User entered '21 Sep 2020' reason for change: Data Entry Error	Stanley Doublin (b) (4)	24 Sep 2020 17:11:59
User entered empty.	(b) (4)	
	Mikayla Frye (b) (4)	04 Sep 2020 21:23:55
	(b) (4)	

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:22:48
User entered empty.	Mikayla Frye (b) (4) (b) (4)	04 Sep 2020 21:23:55

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:01

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 21:23:55

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:01

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:22:48
User entered 'Grade 1/Mild (Grade 1/Mild)'	Mikayla Frye (b) (4) (b) (4)	04 Sep 2020 21:23:55

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:22:48
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	04 Sep 2020 21:23:55

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:01

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:22:48
User entered '0'	Mikayla Frye (b) (4) (b) (4)	04 Sep 2020 21:23:55

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:01

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:22:48
User entered '0'	Mikayla Frye (b) (4) (b) (4)	04 Sep 2020 21:23:55

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:22:48
User entered '0'	Mikayla Frye (b) (4) (b) (4)	04 Sep 2020 21:23:55

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:01

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:22:48
User entered empty.	Mikayla Frye (b) (4) (b) (4)	04 Sep 2020 21:23:55

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:01

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:22:48
User entered empty.	Mikayla Frye (b) (4) (b) (4)	04 Sep 2020 21:23:55

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:22:48
User entered empty.	Mikayla Frye (b) (4) (b) (4)	04 Sep 2020 21:23:55

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:22:48
User entered empty.	Mikayla Frye (b) (4) (b) (4)	04 Sep 2020 21:23:55

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:22:48
User entered '0'	Mikayla Frye (b) (4) (b) (4)	04 Sep 2020 21:23:55

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:22:48
User entered '0'	Mikayla Frye (b) (4) (b) (4)	04 Sep 2020 21:23:55

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:01

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:22:48
User entered '0'	Mikayla Frye (b) (4) (b) (4)	04 Sep 2020 21:23:55

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:22:48
User closed query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	11 Sep 2020 11:58:12
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	10 Sep 2020 14:31:16
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Sep 2020 14:30:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Sep 2020 14:30:06
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Joan Siegner (b) (4)	05 Sep 2020 14:30:06
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 21:23:55
User entered empty.	Mikayla Frye (b) (4)	04 Sep 2020 21:23:55

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:22:48
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Sep 2020 14:30:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Sep 2020 14:30:06
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Joan Siegner (b) (4)	05 Sep 2020 14:30:06
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 21:23:55
User entered empty.	Mikayla Frye (b) (4)	04 Sep 2020 21:23:55

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:01

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:37:17
User closed query 'Dosing discontinued due to this AE. Please consider updating to Investigational product withdrawn' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 15:37:12
Query 'Dosing discontinued due to this AE. Please consider updating to Investigational product withdrawn' answered with 'updated' (Site from CRA).	Cassandra Zehenny (b) (4)	19 Nov 2020 15:14:54
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	19 Nov 2020 15:14:47
User opened query 'Dosing discontinued due to this AE. Please consider updating to Investigational product withdrawn' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 01:36:38
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 01:36:22
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:22:48
User entered 'None (NONE)' reason for change: New Information	Joan Siegner (b) (4)	11 Sep 2020 11:58:12
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 14:31:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Sep 2020 14:31:16
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: New Information	Heather Douds (b) (4)	10 Sep 2020 14:31:16
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 21:23:55
User entered empty.	Mikayla Frye (b) (4)	04 Sep 2020 21:23:55

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:01

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 01:36:18
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 01:35:07
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:22:48
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	05 Sep 2020 14:30:06
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	04 Sep 2020 21:23:55
User entered '0'	Mikayla Frye (b) (4) (b) (4)	04 Sep 2020 21:23:55

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:22:48
User entered '1' reason for change: Data Entry Error	Joan Siegner (b) (4)	05 Sep 2020 14:30:06
User entered '0'	Mikayla Frye (b) (4)	04 Sep 2020 21:23:55

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:22:48
User entered '0'	Mikayla Frye (b) (4) (b) (4)	04 Sep 2020 21:23:55

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:01

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:22:48
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Stanley Doublin (b) (4)	24 Sep 2020 17:11:59
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Sep 2020 14:30:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Sep 2020 14:30:06
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Joan Siegner (b) (4)	05 Sep 2020 14:30:06
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 21:23:55
User entered empty.	Mikayla Frye (b) (4)	04 Sep 2020 21:23:55

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:01

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:22:48
User entered empty.	Mikayla Frye (b) (4) (b) (4)	04 Sep 2020 21:23:55

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:01

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:22:48
User entered empty.	Mikayla Frye (b) (4) (b) (4)	04 Sep 2020 21:23:55

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:01

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	04 Sep 2020 21:23:55

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:34:01

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 21:23:55

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:34:01

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 04:27:52
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:15:21

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:34:01

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: SERTRALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Aug 2020 00:11:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Aug 2020 00:11:48
Data point term sent to Coder	System	14 Aug 2020 20:16:57
User entered 'Sertraline'	Mikayla Frye (b) (4)	14 Aug 2020 20:16:06
	(b) (4)	

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:34:01

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:16:06

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:34:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered 'Anxiety'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:16:06

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:34:01

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered '150'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:16:06

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:34:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered 'mg (mg)'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:16:06

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:34:01

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered empty.	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:16:06

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:34:01

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered 'once daily (QD)'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:16:06

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:34:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered empty.	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:16:06

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:34:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered 'Oral (ORAL)'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:16:06

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:34:01

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered empty.	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:16:06

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	16 Aug 2020 14:05:50
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Date is correct as entered.' (Site from System).	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:33:46
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 20:16:06
User entered 'UN UNK 2004'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:16:06

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:34:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered '0'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:16:06

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:34:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:16:06

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:34:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered empty.	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:16:06

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:34:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:16:06

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:34:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 20:16:06

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:34:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 20:16:06

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:34:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 20:16:06

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:34:01

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS, ATC: CENTRALLY ACTING SYMPATHOMIMETICS, PRODUCT: METHYLPHENIDATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 00:11:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 00:11:52
Data point term sent to Coder	System	14 Aug 2020 20:18:01
User entered 'Methylphenidate'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:17:08

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:34:01

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:17:08

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:34:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered 'Attention Deficit Disorder'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:17:08

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:34:01

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered '54'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:17:08

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:34:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered 'mg (mg)'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:17:08

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:34:01

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered empty.	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:17:08

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:34:01

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered 'once daily (QD)'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:17:08

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:34:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered empty.	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:17:08

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:34:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered 'Oral (ORAL)'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:17:08

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:34:01

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered empty.	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:17:08

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	16 Aug 2020 14:05:54
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Date is correct as entered.' (Site from System).	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:32:32
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 20:17:08
User entered 'UN UNK 2005'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:17:08

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:34:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered '0'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:17:08

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:34:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:17:08

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:34:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered empty.	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:17:08

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:34:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:17:08

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:34:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 20:17:08

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:34:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 20:17:08

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:34:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 20:17:08

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:34:01

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 06:42:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 06:42:16
Data point term sent to Coder	System	14 Aug 2020 21:39:39
Data point term sent to Coder	System	14 Aug 2020 20:19:05
User entered 'Omeprazole'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:18:49

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:34:01

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:18:49

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:34:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered 'Reflux Disease'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:18:49

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:34:01

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 21:38:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Aug 2020 21:38:41
User entered '1' reason for change: Data Entry Error	Mikayla Frye (b) (4)	14 Aug 2020 21:38:41
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 20:18:49
User entered empty.	Mikayla Frye (b) (4)	14 Aug 2020 20:18:49

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:34:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 21:38:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Aug 2020 21:38:47
User entered 'tablet (TABLET)' reason for change: Data Entry Error	Mikayla Frye (b) (4)	14 Aug 2020 21:38:47
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	14 Aug 2020 20:18:49
	Mikayla Frye (b) (4)	14 Aug 2020 20:18:49
	(b) (4)	

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:34:01

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered empty.	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:18:49

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:34:01

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 21:38:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Aug 2020 21:38:56
User entered 'once daily (QD)' reason for change: Data Entry Error	Mikayla Frye (b) (4)	14 Aug 2020 21:38:56
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 20:18:49
User entered empty.	Mikayla Frye (b) (4)	14 Aug 2020 20:18:49

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:34:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered empty.	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:18:49

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:34:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 21:39:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Aug 2020 21:39:03
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Mikayla Frye (b) (4)	14 Aug 2020 21:39:03
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 20:18:49
User entered empty.	Mikayla Frye (b) (4)	14 Aug 2020 20:18:49

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:34:01

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered empty.	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:18:49

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	16 Aug 2020 14:05:59
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Date is correct as entered.' (Site from System).	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:32:15
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 20:18:49
User entered 'UN UNK 2010'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:18:49

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:34:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered '0'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:18:49

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:34:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:18:49

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:34:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered empty.	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:18:49

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:34:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:18:49

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:34:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 21:38:56
User entered empty.	System	14 Aug 2020 20:18:49

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:34:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 21:38:56
User entered empty.	System	14 Aug 2020 20:18:49

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:34:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 21:38:56
User entered empty.	System	14 Aug 2020 20:18:49

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:34:01

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 17:42:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 17:42:17
Data point term sent to Coder Coding entries removed.	System Joan Siegner (b) (4)	06 Oct 2020 17:41:30 06 Oct 2020 17:40:54
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 06:49:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 06:49:17
Data point term sent to Coder	System	14 Aug 2020 20:31:32
Data point term sent to Coder	System	14 Aug 2020 20:21:10
User entered 'Naproxen'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:20:23

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:34:01

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:20:23

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:34:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User closed query ' Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF." ' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 11:29:04
Query ' Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF." ' answered with 'information pending' (Site from DM).	Joan Siegner (b) (4)	06 Oct 2020 17:42:42
User entered 'BACK PAIN' reason for change: Data Entry Error	Joan Siegner (b) (4)	06 Oct 2020 17:40:54
User opened query ' Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF." ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 13:52:51
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 20:30:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Aug 2020 20:30:41
User entered 'Backpain' reason for change: Data Entry Error	Mikayla Frye (b) (4)	14 Aug 2020 20:30:41
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 20:20:23
User entered empty.	Mikayla Frye (b) (4)	14 Aug 2020 20:20:23

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:34:01

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User closed query ""Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 08:59:11
Query ""Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'dosage unknown; self-reported' (Site from DM).	Joan Siegner (b) (4)	06 Oct 2020 17:42:34
User opened query ""Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 13:52:54
User entered '1'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:20:23

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:34:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered 'tablet (TABLET)'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:20:23

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:34:01

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered empty.	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:20:23

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:34:01

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered 'as needed (PRN)'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:20:23

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:34:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered empty.	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:20:23

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:34:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 20:30:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Aug 2020 20:30:51
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Mikayla Frye (b) (4)	14 Aug 2020 20:30:51
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 20:20:23
User entered empty.	Mikayla Frye (b) (4)	14 Aug 2020 20:20:23

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:34:01

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered empty.	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:20:23

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	14 Aug 2020 20:31:05
User entered '11 Aug 2020' reason for change: Data Entry Error	Mikayla Frye (b) (4)	14 Aug 2020 20:31:05
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	
User entered empty.	System	14 Aug 2020 20:20:23
	Mikayla Frye (b) (4)	14 Aug 2020 20:20:23
	(b) (4)	

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:34:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered '0'	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:20:23

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:34:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 20:31:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Aug 2020 20:31:13
User entered 'Yes (Y)' reason for change: Data Entry Error	Mikayla Frye (b) (4)	14 Aug 2020 20:31:13
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 20:20:23
User entered empty.	Mikayla Frye (b) (4)	14 Aug 2020 20:20:23

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:34:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered empty.	Mikayla Frye (b) (4) (b) (4)	14 Aug 2020 20:20:23

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:34:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 20:31:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Aug 2020 20:31:18
User entered 'No (N)' reason for change: Data Entry Error	Mikayla Frye (b) (4)	14 Aug 2020 20:31:18
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 20:20:23
User entered empty.	Mikayla Frye (b) (4)	14 Aug 2020 20:20:23

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:34:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 20:20:23

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:34:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 20:20:23

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:34:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 20:20:23

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:34:01

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE RELATED DRUGS, PRODUCT: ESZOPICLONE, PRODUCTSYNONYM: LUNESTA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 20:35:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 20:35:31
Data point term sent to Coder	System	21 Aug 2020 20:34:46
User entered 'lunesta'	Mikayla Frye (b) (4) (b) (4)	21 Aug 2020 20:34:35

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:34:01

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	21 Aug 2020 20:34:35

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:34:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered 'insomnia'	Mikayla Frye (b) (4) (b) (4)	21 Aug 2020 20:34:35

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:34:01

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered '0.5'	Mikayla Frye (b) (4) (b) (4)	21 Aug 2020 20:34:35

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:34:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered 'tablet (TABLET)'	Mikayla Frye (b) (4) (b) (4)	21 Aug 2020 20:34:35

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:34:01

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered empty.	Mikayla Frye (b) (4) (b) (4)	21 Aug 2020 20:34:35

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:34:01

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered 'as needed (PRN)'	Mikayla Frye (b) (4) (b) (4)	21 Aug 2020 20:34:35

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:34:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered empty.	Mikayla Frye (b) (4) (b) (4)	21 Aug 2020 20:34:35

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:34:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered 'Oral (ORAL)'	Mikayla Frye (b) (4) (b) (4)	21 Aug 2020 20:34:35

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:34:01

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered empty.	Mikayla Frye (b) (4) (b) (4)	21 Aug 2020 20:34:35

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered '13 Aug 2020'	Mikayla Frye (b) (4) (b) (4)	21 Aug 2020 20:34:35

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:34:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered '0'	Mikayla Frye (b) (4) (b) (4)	21 Aug 2020 20:34:35

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:34:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered 'Yes (Y)'	Mikayla Frye (b) (4) (b) (4)	21 Aug 2020 20:34:35

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:34:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered empty.	Mikayla Frye (b) (4) (b) (4)	21 Aug 2020 20:34:35

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:34:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	21 Aug 2020 20:34:35

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:34:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 20:34:35

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:34:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 20:34:35

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:34:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 20:34:35

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:34:01

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User closed query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening) (for corticosteroids ≥ 20 mg/day of prednisone equivalent).' (Site from DM). Query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening) (for corticosteroids ≥ 20 mg/day of prednisone equivalent).' answered with 'Did not equal >14 days. Tapered dose from 24mg to 4mg over 6 days' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 04:22:30
User opened query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening) (for corticosteroids ≥ 20 mg/day of prednisone equivalent).' (Site from DM).	Cassandra Zehenny (b) (4)	21 Oct 2020 14:47:53
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	(b) (4), (b) (6)	20 Oct 2020 15:03:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Sep 2020 07:15:44
Data point term sent to Coder	(b) (4)	
User entered 'prednisone'	System	04 Sep 2020 21:20:31
	Mikayla Frye (b) (4)	04 Sep 2020 21:20:31
	(b) (4)	

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:34:01

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	04 Sep 2020 21:20:31

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:34:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered 'shingles'	Mikayla Frye (b) (4) (b) (4)	04 Sep 2020 21:20:31

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:34:01

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered '24-4' reason for change: New Information	Cassandra Zehenny (b) (4)	21 Oct 2020 14:47:32
User closed query 'Per DM CLR: Please note, the dosage administered cannot be verified as entered as more than one formulation is available for this medication. Please confirm and update the Dose and Unit fields accordingly. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 09:09:37
Query 'Per DM CLR: Please note, the dosage administered cannot be verified as entered as more than one formulation is available for this medication. Please confirm and update the Dose and Unit fields accordingly. ' answered with 'tapering dosage' (Site from DM).	Joan Siegner (b) (4)	03 Oct 2020 17:56:48
User entered '24' reason for change: Data Entry Error	Joan Siegner (b) (4)	03 Oct 2020 17:56:31
User opened query 'Per DM CLR: Please note, the dosage administered cannot be verified as entered as more than one formulation is available for this medication. Please confirm and update the Dose and Unit fields accordingly. ' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 16:17:53
User entered '24-4'	Mikayla Frye (b) (4)	04 Sep 2020 21:20:31

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:34:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered 'mg (mg)'	Mikayla Frye (b) (4) (b) (4)	04 Sep 2020 21:20:31

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:34:01

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered empty.	Mikayla Frye (b) (4) (b) (4)	04 Sep 2020 21:20:31

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:34:01

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered 'once daily (QD)'	Mikayla Frye (b) (4) (b) (4)	04 Sep 2020 21:20:31

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:34:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered empty.	Mikayla Frye (b) (4) (b) (4)	04 Sep 2020 21:20:31

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:34:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered 'Oral (ORAL)'	Mikayla Frye (b) (4) (b) (4)	04 Sep 2020 21:20:31

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:34:01

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered empty.	Mikayla Frye (b) (4) (b) (4)	04 Sep 2020 21:20:31

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered '04 Sep 2020' reason for change: Data Entry Error	Cassandra Zehenny (b) (4)	21 Oct 2020 14:47:32
User entered '14 Aug 2020'	Mikayla Frye (b) (4)	04 Sep 2020 21:20:31

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:34:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered '0'	Mikayla Frye (b) (4) (b) (4)	04 Sep 2020 21:20:31

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:34:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered 'No (N)' reason for change: New Information	Cassandra Zehenny (b) (4)	21 Oct 2020 14:47:32
User entered 'Yes (Y)' reason for change: Data Entry Error	Joan Siegner (b) (4)	05 Sep 2020 14:27:37
User entered 'No (N)' reason for change: Data Entry Error	Mikayla Frye (b) (4)	04 Sep 2020 21:20:37
User entered 'Yes (Y)'	Mikayla Frye (b) (4)	04 Sep 2020 21:20:31

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:34:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered '09 Sep 2020' reason for change: New Information	Cassandra Zehenny (b) (4)	21 Oct 2020 14:47:32
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	(b) (4)	05 Sep 2020 14:27:51
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	05 Sep 2020 14:27:51
User entered empty; reason for change Data Entry Error	Joan Siegner (b) (4)	05 Sep 2020 14:27:51
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	05 Sep 2020 14:27:37
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	04 Sep 2020 21:20:37
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	04 Sep 2020 21:20:31
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	04 Sep 2020 21:20:31
User entered '09 Sep 2020'	Mikayla Frye (b) (4)	04 Sep 2020 21:20:31

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:34:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	04 Sep 2020 21:20:31

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:34:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 21:20:31

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:34:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 21:20:31

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:34:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Sep 2020 21:20:31

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:34:01

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: VALACICLOVIR, PRODUCTSYNONYM: VALACYCLOVIR [VALACICLOVIR] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 07:32:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 07:32:48
Data point term sent to Coder	System	04 Sep 2020 21:21:32
User entered 'Valacyclovir'	Mikayla Frye (b) (4) (b) (4)	04 Sep 2020 21:21:31

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:34:01

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	04 Sep 2020 21:21:31

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:34:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered 'shingles'	Mikayla Frye (b) (4) (b) (4)	04 Sep 2020 21:21:31

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:34:01

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User closed query 'Per DM CLR: Please review the dose and unit recorded as this is not the standard dose for this medication. Please correct the dosage and unit or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 05:22:05
Query 'Per DM CLR: Please review the dose and unit recorded as this is not the standard dose for this medication. Please correct the dosage and unit or provide explanation for alternate dosage. ' answered with 'done' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 17:04:36
User entered '1 mg' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 17:04:27
User opened query 'Per DM CLR: Please review the dose and unit recorded as this is not the standard dose for this medication. Please correct the dosage and unit or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 05:16:50
User entered '1'	Mikayla Frye (b) (4) (b) (4)	04 Sep 2020 21:21:31

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:34:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered 'mg (mg)'	Mikayla Frye (b) (4) (b) (4)	04 Sep 2020 21:21:31

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:34:01

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered empty.	Mikayla Frye (b) (4) (b) (4)	04 Sep 2020 21:21:31

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:34:01

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered 'three times daily (TID)'	Mikayla Frye (b) (4) (b) (4)	04 Sep 2020 21:21:31

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:34:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered empty.	Mikayla Frye (b) (4) (b) (4)	04 Sep 2020 21:21:31

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:34:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered 'Oral (ORAL)'	Mikayla Frye (b) (4) (b) (4)	04 Sep 2020 21:21:31

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:34:01

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered empty.	Mikayla Frye (b) (4) (b) (4)	04 Sep 2020 21:21:31

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered '04 Sep 2020'	Mikayla Frye (b) (4) (b) (4)	04 Sep 2020 21:21:31

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:34:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered '0'	Mikayla Frye (b) (4) (b) (4)	04 Sep 2020 21:21:31

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:34:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered 'No (N)' reason for change: Data Entry Error	Stanley Doublin (b) (4)	22 Sep 2020 18:40:57
User entered 'Yes (Y)' reason for change: Data Entry Error	Joan Siegner (b) (4)	05 Sep 2020 14:29:17
User entered 'No (N)'	Mikayla Frye (b) (4)	04 Sep 2020 21:21:31

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:34:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered '14 Sep 2020' reason for change: Data Entry Error	Stanley Doublin (b) (4)	22 Sep 2020 18:40:57
User closed query 'Future date has been entered. Please correct.' (Site from System).	(b) (4)	
User entered empty; reason for change Data Entry Error	System	05 Sep 2020 14:29:17
	Joan Siegner (b) (4)	05 Sep 2020 14:29:17
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	04 Sep 2020 21:21:31
User entered '14 Sep 2020'	Mikayla Frye (b) (4)	04 Sep 2020 21:21:31
	(b) (4)	

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:34:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:12:21
User entered 'No (N)'	Mikayla Frye (b) (4) (b) (4)	04 Sep 2020 21:21:31

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:34:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	04 Sep 2020 21:21:31

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:34:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 21:21:31

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:34:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Sep 2020 21:21:31

US3552035

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:34:01

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:54:33
User closed query 'Please change date to 08Sep' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 18:54:24
User entered '17 Sep 2020' reason for change: Data Entry Error	Joan Siegner (b) (4)	11 Nov 2020 17:41:09
Query 'Please change date to 08Sep' answered with 'data corrected' (Site from CRA).	Joan Siegner (b) (4)	11 Nov 2020 17:24:33
User entered '08 Sep 2020' reason for change: Data Entry Error	Joan Siegner (b) (4)	11 Nov 2020 17:24:26
User opened query 'Please change date to 08Sep' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 16:32:51
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 22:15:38
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:06:19
User entered '8 Sep 2020'	Heather Douds (b) (4)	14 Sep 2020 15:32:10

US3552035

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:34:01

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:06:19
User entered 'AE (specify) (ADVERSE EVENT)'	Heather Douds (b) (4) (b) (4)	14 Sep 2020 15:32:10

US3552035

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:34:01

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

Audit	User	Time (GMT)
User closed query 'Per CDM: Please record AE record number instead of details ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 10:02:55
	(b) (4), (b) (6)	18 Nov 2020 20:03:02
Query 'Per CDM: Please record AE record number instead of details ' answered with 'updated' (Site from DM). DataPoint Un-verified.	Cassandra Zehenny (b) (4)	18 Nov 2020 16:17:26
	Cassandra Zehenny (b) (4)	18 Nov 2020 16:17:23
User entered 'AE #1' reason for change: Per Query Resolution	Cassandra Zehenny (b) (4)	18 Nov 2020 16:17:23
User opened query 'Per CDM: Please record AE record number instead of details ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:14:49
	(b) (4), (b) (6)	10 Nov 2020 22:06:19
User closed query 'Please consider adding Shingles vaccination to Concomitant medication eCRF and also source if not done already. Thank you! ' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 13:40:20
Query 'Please consider adding Shingles vaccination to Concomitant medication eCRF and also source if not done already. Thank you! ' answered with 'subject had diagnosis of shingles infection not vaccination' (Site from CRA).	Stanley Dublin (b) (4)	22 Sep 2020 18:41:44
User opened query 'Please consider adding Shingles vaccination to Concomitant medication eCRF and also source if not done already. Thank you! ' (Site from CRA).	(b) (4), (b) (6)	21 Sep 2020 18:18:45
User entered 'Second vaccination held due to diagnosis of shingles infection'	Heather Douds (b) (4)	14 Sep 2020 15:32:10