

US3952158 (Prod: Synexus - Optimal Research - Rockville)

Generated By: KC Joubran

Generated On: 12 Aug 2021 13:40:43

All time stamps listed in this document are displayed in GMT

US3952158

Form: Participant Creation

Data signed: (b) (4) 08 Apr 2021 20:24:21

Generated On: 12 Aug 2021 13:40:43

[Participant ID](#)

US3952158

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

US3952158

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 22:10:23

Generated On: 12 Aug 2021 13:40:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 22:11:56

Generated On: 12 Aug 2021 13:40:43

Date of Birth (MMM yyyy)	(b) (6) 1979
Age	41
Age Units	YEARS
Age (Derived)	41
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	True
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 22:11:56

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Date of Informed Consent (<i>dd MMM yyyy</i>)	28 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input checked="" type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 22:11:56

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 22:10:23

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Feb 2021 22:10:23

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Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2011
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2011
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2011
Start Year (derived)	2011
Stop Month and Year (derived)	JAN 2011
Stop Year (derived)	2011

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 22:10:23

Generated On: 12 Aug 2021 13:40:43

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	28 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	08:55 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 08:55
Height (<i>xxx.x</i>)	69.0 in
Weight (<i>xxx.x</i>)	155.0 lb
BMI (<i>xxx.x</i>)	22.93736 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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

Data signed: (b) (4) 19 Feb 2021 22:10:23

Generated On: 12 Aug 2021 13:40:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 SEP 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 22:10:23

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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 ACTIVELY WORKING ROOFER

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 22:10:23

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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	True
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 22:10:23

Generated On: 12 Aug 2021 13:40:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 22:10:23

Generated On: 12 Aug 2021 13:40:43

What was the date of randomization? (dd MMM yyyy) 28 SEP 2020

What was the participant's randomization number? 115687

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 22:10:23

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Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 22:10:23

Generated On: 12 Aug 2021 13:40:43

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 SEP 2020
Time of assessment (00:00-23:59)	08:55 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 08:55
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	97 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	150 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	102 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 22:10:23

Generated On: 12 Aug 2021 13:40:43

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 SEP 2020
Time of assessment (00:00-23:59)	11:11 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 11:11
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 22:10:23

Generated On: 12 Aug 2021 13:40:43

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 22:10:23

Generated On: 12 Aug 2021 13:40:43

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 28 SEP 2020

What was the treatment time? (00:00-23:59) 10:35 (24 HR)

Treatment Date and Time (derived) 28 SEP 2020 10:35

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 22:10:23

Generated On: 12 Aug 2021 13:40:43

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 SEP 2020

Collection time (00:00-23:59)

09:50 (24 HR)

Collection date and time (derived)

28 SEP 2020 09:50

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 22:10:23

Generated On: 12 Aug 2021 13:40:43

Collection date (<i>dd MMM yyyy</i>)			28 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:44	28 SEP 2020 09:44
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:10:23

Generated On: 12 Aug 2021 13:40:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 SEP 2020 11:13

PC Open Date & Time

28 SEP 2020 10:55

PC Close Date & Time

28 SEP 2020 13:25

US3952158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.7 °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	28 SEP 2020 16:58
PC Open Date & Time	28 SEP 2020 14:20
PC Close Date & Time	29 SEP 2020 11:59

US3952158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 SEP 2020 14:16

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3952158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 SEP 2020 12:14

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3952158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °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

01 OCT 2020 13:38

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3952158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 OCT 2020 17:20

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3952158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 OCT 2020 17:32

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3952158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

04 OCT 2020 18:32

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:40:43

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 ☒

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

28 SEP 2020 11:18

PC Open Date & Time

28 SEP 2020 10:55

PC Close Date & Time

28 SEP 2020 13:25

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 SEP 2020 16:59

PC Open Date & Time

28 SEP 2020 14:20

PC Close Date & Time

29 SEP 2020 11:59

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 SEP 2020 14:17

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 SEP 2020 12:14

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 OCT 2020 13:39

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 OCT 2020 17:20

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 OCT 2020 17:32

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 OCT 2020 18:32

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:40:43

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

No ☒

Yes ☐

PC Time stamp	28 SEP 2020 11:19
PC Open Date & Time	28 SEP 2020 10:55
PC Close Date & Time	28 SEP 2020 13:25

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:40:43

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

No ☒

Yes ☐

PC Time stamp	28 SEP 2020 17:00
PC Open Date & Time	28 SEP 2020 14:20
PC Close Date & Time	29 SEP 2020 11:59

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:40:43

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 14:17
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:40:43

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 12:15
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:40:43

Yes <input type="checkbox"/>	
PC Time stamp	01 OCT 2020 13:39
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

48 of 1352

EAB) (1725)

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:40:43

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 17:21
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

50 of 1352

EAB) (1725)

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:40:43

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 17:33
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:40:43

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 18:32
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3952158

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:11:56

Generated On: 12 Aug 2021 13:40:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3952158

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:11:56

Generated On: 12 Aug 2021 13:40:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952158

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:11:56

Generated On: 12 Aug 2021 13:40:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3952158

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:11:56

Generated On: 12 Aug 2021 13:40:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952158

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:11:56

Generated On: 12 Aug 2021 13:40:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 OCT 2020

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

NO RESPONSE AFTER FOUR
ATTEMPTS TO REACH SUBJECT

If Contact Not Made, please provide Comments

US3952158

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:11:56

Generated On: 12 Aug 2021 13:40:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952158

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 22:10:24

Generated On: 12 Aug 2021 13:40:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3952158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 22:10:24

Generated On: 12 Aug 2021 13:40:43

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 OCT 2020
Time of assessment (00:00-23:59)	10:11 (24 HR)
Vital Signs Date and Time (derived)	26 OCT 2020 10:11
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	104 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	101 mmHg
Diastolic Blood Pressure units	MMHG

US3952158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 22:10:24

Generated On: 12 Aug 2021 13:40:43

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

US3952158

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 22:10:24

Generated On: 12 Aug 2021 13:40:43

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3952158

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 22:10:24

Generated On: 12 Aug 2021 13:40:43

Was study treatment given? Yes ☐
No ☒

If No, reason not given

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

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

What was the study treatment?

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?

US3952158

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 22:10:24

Generated On: 12 Aug 2021 13:40:43

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

26 OCT 2020

Collection time (00:00-23:59)

12:09 (24 HR)

Collection date and time (derived)

26 OCT 2020 12:09

US3952158

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 22:10:24

Generated On: 12 Aug 2021 13:40:43

Collection date (dd MMM yyyy)			26 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:14	26 OCT 2020 12:14
Nasopharyngeal Swab 2	No		

US3952158

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:10:24

Generated On: 12 Aug 2021 13:40:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952158

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 21:46:39

Generated On: 12 Aug 2021 13:40:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3952158

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:46:39

Generated On: 12 Aug 2021 13:40:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952158

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:11:56

Generated On: 12 Aug 2021 13:40:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3952158

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:11:56

Generated On: 12 Aug 2021 13:40:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952158

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:11:56

Generated On: 12 Aug 2021 13:40:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3952158

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:11:56

Generated On: 12 Aug 2021 13:40:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952158

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 22:10:24

Generated On: 12 Aug 2021 13:40:43

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

US3952158

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 22:10:24

Generated On: 12 Aug 2021 13:40:43

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	23 NOV 2020
Time of assessment (<i>00:00-23:59</i>)	09:05 (24 HR)
Vital Signs Date and Time (derived)	23 NOV 2020 09:05
Temperature (<i>xxx.x</i>)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	97 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	94 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3952158

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 22:10:24

Generated On: 12 Aug 2021 13:40:43

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3952158

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 22:10:24

Generated On: 12 Aug 2021 13:40:43

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 NOV 2020

Collection time (00:00-23:59)

09:35 (24 HR)

Collection date and time (derived)

23 NOV 2020 09:35

US3952158

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:10:24

Generated On: 12 Aug 2021 13:40:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2020 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

Date and time of submission

Patient Cloud Open Date & Time	02 DEC 2020 00:01
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Patient Cloud Close Date & Time	06 DEC 2020 23:59
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US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 DEC 2020 06:47:33
Patient Cloud Open Date & Time	09 DEC 2020 00:01
Patient Cloud Close Date & Time	13 DEC 2020 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 82

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 DEC 2020 11:14:37

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 DEC 2020 07:00:56
Patient Cloud Open Date & Time	23 DEC 2020 00:01
Patient Cloud Close Date & Time	27 DEC 2020 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 DEC 2020 08:24:56
Patient Cloud Open Date & Time	30 DEC 2020 00:01
Patient Cloud Close Date & Time	03 JAN 2021 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 JAN 2021 18:44:13

Patient Cloud Open Date & Time

06 JAN 2021 00:01

Patient Cloud Close Date & Time

10 JAN 2021 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 JAN 2021 01:00:11
Patient Cloud Open Date & Time	13 JAN 2021 00:01
Patient Cloud Close Date & Time	17 JAN 2021 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 JAN 2021 21:10:46

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 JAN 2021 02:38:36
Patient Cloud Open Date & Time	27 JAN 2021 00:01
Patient Cloud Close Date & Time	31 JAN 2021 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 FEB 2021 15:27:23
Patient Cloud Open Date & Time	03 FEB 2021 00:01
Patient Cloud Close Date & Time	07 FEB 2021 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 FEB 2021 14:40:03

Patient Cloud Open Date & Time

10 FEB 2021 00:01

Patient Cloud Close Date & Time

14 FEB 2021 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 FEB 2021 20:57:01
Patient Cloud Open Date & Time	17 FEB 2021 00:01
Patient Cloud Close Date & Time	21 FEB 2021 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 FEB 2021 15:04:30

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 MAR 2021 18:37:24

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 MAR 2021 13:52:27
Patient Cloud Open Date & Time	10 MAR 2021 00:01
Patient Cloud Close Date & Time	14 MAR 2021 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 MAR 2021 06:26:11

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 MAR 2021 02:06:17

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 MAR 2021 08:23:00

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 APR 2021 10:32:18

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 APR 2021 06:48:48

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 APR 2021 22:29:56

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 APR 2021 13:31:01

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 222

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 229

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

[Patient Cloud Open Date & Time](#)

12 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 236

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 243

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 264

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 JUN 2021 00:01
Patient Cloud Close Date & Time	20 JUN 2021 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

[Patient Cloud Open Date & Time](#)

23 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

[Patient Cloud Open Date & Time](#)

30 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 285

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

[Patient Cloud Open Date & Time](#)

07 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 292

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 JUL 2021 00:01
Patient Cloud Close Date & Time	18 JUL 2021 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 JUL 2021 00:01
Patient Cloud Close Date & Time	25 JUL 2021 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

[Patient Cloud Open Date & Time](#)

11 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 327

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

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 334

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

[Patient Cloud Open Date & Time](#)

25 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2021 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

[Patient Cloud Open Date & Time](#)

01 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

[Patient Cloud Open Date & Time](#)

15 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2021 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

[Patient Cloud Open Date & Time](#)

22 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

[Patient Cloud Open Date & Time](#)

06 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

Patient Cloud Open Date & Time	13 OCT 2021 00:01
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Patient Cloud Close Date & Time	17 OCT 2021 23:59
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US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 390

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

[Patient Cloud Open Date & Time](#)

20 OCT 2021 00:01

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24 OCT 2021 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 OCT 2021 00:01
Patient Cloud Close Date & Time	31 OCT 2021 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 404

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

[Patient Cloud Open Date & Time](#)

03 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

Patient Cloud Open Date & Time	10 NOV 2021 00:01
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Patient Cloud Close Date & Time	14 NOV 2021 23:59
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US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

[Patient Cloud Open Date & Time](#)

24 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

[Patient Cloud Open Date & Time](#)

01 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

05 DEC 2021 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

[Patient Cloud Open Date & Time](#)

08 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

12 DEC 2021 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 446

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 DEC 2021 00:01
Patient Cloud Close Date & Time	19 DEC 2021 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 DEC 2021 00:01
Patient Cloud Close Date & Time	26 DEC 2021 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 460

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	29 DEC 2021 00:01
Patient Cloud Close Date & Time	02 JAN 2022 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

[Patient Cloud Open Date & Time](#)

05 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 474

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

[Patient Cloud Open Date & Time](#)

12 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 JAN 2022 00:01
Patient Cloud Close Date & Time	30 JAN 2022 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	02 FEB 2022 00:01
Patient Cloud Close Date & Time	06 FEB 2022 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

[Patient Cloud Open Date & Time](#)

09 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 509

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

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

[Patient Cloud Open Date & Time](#)

16 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

[Patient Cloud Open Date & Time](#)

23 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

27 FEB 2022 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

[Patient Cloud Open Date & Time](#)

02 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

[Patient Cloud Open Date & Time](#)

23 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAR 2022 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

[Patient Cloud Open Date & Time](#)

06 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 565

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Date and time of submission

[Patient Cloud Open Date & Time](#)

13 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 APR 2022 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Date and time of submission

[Patient Cloud Open Date & Time](#)

20 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 APR 2022 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 579

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

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

[Patient Cloud Open Date & Time](#)

04 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

[Patient Cloud Open Date & Time](#)

11 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 600

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

No ☐
Yes ☐

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

No ☐
Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐
Yes ☐

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐
Yes ☐

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

[Patient Cloud Open Date & Time](#)

25 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

[Patient Cloud Open Date & Time](#)

01 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 621

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

[Patient Cloud Open Date & Time](#)

08 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

[Patient Cloud Open Date & Time](#)

15 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUN 2022 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 JUN 2022 00:01
Patient Cloud Close Date & Time	26 JUN 2022 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

[Patient Cloud Open Date & Time](#)

29 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

[Patient Cloud Open Date & Time](#)

06 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUL 2022 00:01

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17 JUL 2022 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 670

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 JUL 2022 00:01
Patient Cloud Close Date & Time	31 JUL 2022 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

[Patient Cloud Open Date & Time](#)

03 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

Patient Cloud Open Date & Time	10 AUG 2022 00:01
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Patient Cloud Close Date & Time	14 AUG 2022 23:59
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US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

[Patient Cloud Open Date & Time](#)

17 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

28 AUG 2022 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

[Patient Cloud Open Date & Time](#)

07 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

[Patient Cloud Open Date & Time](#)

14 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

[Patient Cloud Open Date & Time](#)

21 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	05 OCT 2022 00:01
Patient Cloud Close Date & Time	09 OCT 2022 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

Date and time of submission	
Patient Cloud Open Date & Time	19 OCT 2022 00:01
Patient Cloud Close Date & Time	23 OCT 2022 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

[Patient Cloud Open Date & Time](#)

26 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

30 OCT 2022 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 768

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

06 NOV 2022 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

13 NOV 2022 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 782

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

[Patient Cloud Open Date & Time](#)

16 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

20 NOV 2022 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

27 NOV 2022 23:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

04 DEC 2022 23:59

US3952158

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 12 Aug 2021 13:40:43

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		04 MAR 2021 18:37:10

US3952158

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 21:46:39

Generated On: 12 Aug 2021 13:40:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3952158

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:46:39

Generated On: 12 Aug 2021 13:40:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952158

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 20:24:21

Generated On: 12 Aug 2021 13:40:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3952158

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 20:24:21

Generated On: 12 Aug 2021 13:40:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952158

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 20:24:21

Generated On: 12 Aug 2021 13:40:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 FEB 2021

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

MESSAGE LEFT FOR SUBJECT
WHO NEVER RETURNED CALL

If Contact Not Made, please provide Comments

US3952158

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 20:24:21

Generated On: 12 Aug 2021 13:40:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952158

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 20:24:21

Generated On: 12 Aug 2021 13:40:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3952158

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 20:24:21

Generated On: 12 Aug 2021 13:40:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952158

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:40:43

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

Was visit performed at the participant's home or at the clinic? Home ☐
Clinic ☐

Folder OID _____

US3952158

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
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 <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
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)	

US3952158

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:40:43

Was the physical examination performed?

Yes ☐

No ☐

Date of examination (dd MMM yyyy)

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3952158

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:40:43

Was the sample collected? Yes ☐
No ☐

Collection date (*dd MMM yyyy*) _____
Collection time (*00:00-23:59*) _____
Collection date and time (derived) _____

US3952158

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:40:43

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3952158

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:40:43

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

US3952158

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 12 Aug 2021 13:40:43

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3952158

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:40:43

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

Was visit performed at the participant's home or at the clinic? Home ☐
Clinic ☐

Folder OID _____

US3952158

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:40:43

Date of updated informed consent (<i>dd MMM yyyy</i>)		
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study		
Was the participant unblinded?	Yes	<input type="checkbox"/>
	No	<input type="checkbox"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5	<input type="checkbox"/>
	Amendment 6 or later	<input type="checkbox"/>
Date of unblinding (<i>dd MMM yyyy</i>)		
Participant randomization assignment	mRNA-1273	<input type="checkbox"/>
	Placebo	<input type="checkbox"/>
Actual Dose 1	mRNA-1273	<input type="checkbox"/>
	Placebo	<input type="checkbox"/>
	Not Administered	<input type="checkbox"/>
Actual Dose 2	mRNA-1273	<input type="checkbox"/>
	Placebo	<input type="checkbox"/>
	Not Administered	<input type="checkbox"/>
Will participant receive mRNA-1273?	Yes	<input type="checkbox"/>
	No	<input type="checkbox"/>
Placebo Only Flag		
Continuing with mRNA-1273		

US3952158

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:40:43

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date (<i>dd MMM yyyy</i>)	<hr/>
Collection time (<i>00:00-23:59</i>)	<hr/>
Collection date and time (derived)	<hr/>

US3952158

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:40:43

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

Collection date (<i>dd MMM yyyy</i>)	_____
Collection time (<i>00:00 - 23:59</i>)	_____
Collection Date and Time (derived)	_____

US3952158

Folder: Unscheduled 26 Oct 2020

Form: Unscheduled Visit Assessment

Data signed: (b) (4) 08 Apr 2021 20:24:22

Generated On: 12 Aug 2021 13:40:43

Visit Date	26 OCT 2020
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Please check all assessments that apply for this visit

Physical Exam	False
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Vital Signs	True
-------------	------

Immunogenicity Assessment	False
---------------------------	-------

Pregnancy Test	False
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US3952158

Folder: Unscheduled 26 Oct 2020

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 20:24:22

Generated On: 12 Aug 2021 13:40:43

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	26 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	10:28 (24 HR)
Vital Signs Date and Time (derived)	26 OCT 2020 10:28
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	103 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	101 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3952158

Folder: Unscheduled 26 Oct 2020

Form: Unscheduled Visit Assessment

Data signed: (b) (4) 08 Apr 2021 20:24:22

Generated On: 12 Aug 2021 13:40:43

Visit Date	26 OCT 2020
------------	-------------

Please check all assessments that apply for this visit

Physical Exam	False
---------------	-------

Vital Signs	True
-------------	------

Immunogenicity Assessment	False
---------------------------	-------

Pregnancy Test	False
----------------	-------

US3952158

Folder: Unscheduled 26 Oct 2020

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 20:24:22

Generated On: 12 Aug 2021 13:40:43

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	26 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	11:35 (24 HR)
Vital Signs Date and Time (derived)	26 OCT 2020 11:35
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	104 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	153 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	108 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3952158

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 08 Apr 2021 19:12:34

Generated On: 12 Aug 2021 13:40:43

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3952158

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 07 Apr 2021 21:23:01

Generated On: 12 Aug 2021 13:40:43

AEID

Adverse event

ELEVATED DIASTOLIC BLOOD
PRESSURE

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)

26 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

23 NOV 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 ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3952158

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 07 Apr 2021 21:23:01

Generated On: 12 Aug 2021 13:40:43

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3952158

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 07 Apr 2021 21:23:01

Generated On: 12 Aug 2021 13:40:43

AEID	
Adverse event	TOOTH ACHE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	14 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

US3952158

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 07 Apr 2021 21:23:01

Generated On: 12 Aug 2021 13:40:43

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3952158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 08 Apr 2021 20:24:21

Generated On: 12 Aug 2021 13:40:43

Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

US3952158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 20:24:21

Generated On: 12 Aug 2021 13:40:43

Name of Medication ADVIL

Prophylaxis Yes ☐
No ☒

Indication TOOTH ACHE

Dose per administration 400

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3952158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 20:24:21

Generated On: 12 Aug 2021 13:40:43

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		14 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3952158

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 08 Apr 2021 20:24:21

Generated On: 12 Aug 2021 13:40:43

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3952158

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 08 Apr 2021 20:24:21

Generated On: 12 Aug 2021 13:40:43

Date of dosing discontinuation (dd MMM yyyy) 26 OCT 2020

Primary reason for dosing discontinuation

AE (specify)	<input checked="" type="radio"/>
SAE (specify)	<input type="radio"/>
Death	<input type="radio"/>
Lost To Follow-up	<input type="radio"/>
Physician decision (specify)	<input type="radio"/>
Pregnancy	<input type="radio"/>
Protocol deviation (specify)	<input type="radio"/>
Study Terminated By Sponsor	<input type="radio"/>
Withdrawal of consent by participant (specify)	<input type="radio"/>
Due to SARS-COV-2	<input type="radio"/>
Other	<input type="radio"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify #1

US3952158

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:40:43

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

Audit

US3952158 (Prod: Synexus - Optimal Research - Rockville)

US3952158

Form: Participant Creation

Generated On: 12 Aug 2021 13:40:43

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
User entered 'US3952158'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	28 Sep 2020 13:22:50

US3952158

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:40:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:37:51

US3952158

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:40:43

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered '28 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Sep 2020 13:22:51

US3952158

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:40:43

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered 'Clinic (Clinic)'	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:37:51

US3952158

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:40:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User entered 'SCRN'	System	30 Sep 2020 14:37:51

US3952158

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:40:43

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:11:56
User entered (b) (6) 1979'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Sep 2020 13:22:52

US3952158

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:40:43

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:11:56
User entered '41'	Nick Bart (b) (4)	30 Sep 2020 14:38:05

US3952158

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:40:43

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User entered 'YEARS'	System	30 Sep 2020 14:38:05

US3952158

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:40:43

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User entered '41'	System	28 Sep 2020 14:58:27

US3952158

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:40:43

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:11:56
User entered 'Male (M)'	Nick Bart (b) (4)	30 Sep 2020 14:38:05

US3952158

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:40:43

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:11:56
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:38:05

US3952158

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:40:43

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:11:56
User entered '0'	Nick Bart (b) (4)	30 Sep 2020 14:38:05

US3952158

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:40:43

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:11:56
User entered 'I'	Nick Bart (b) (4)	30 Sep 2020 14:38:05

US3952158

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:40:43

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:11:56
User entered '0'	Nick Bart (b) (4)	30 Sep 2020 14:38:05

US3952158

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:40:43

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:11:56
User entered '0'	Nick Bart (b) (4)	30 Sep 2020 14:38:05

US3952158

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:40:43

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:11:56
User entered '0'	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:38:05

US3952158

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:40:43

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:11:56
User entered '0'	Nick Bart (b) (4)	30 Sep 2020 14:38:05

US3952158

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:40:43

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:11:56
User entered empty.	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:38:05

US3952158

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:40:43

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:11:56
User entered '0'	Nick Bart (b) (4)	30 Sep 2020 14:38:05

US3952158

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:40:43

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:11:56
User entered '0'	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:38:05

US3952158

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:40:43

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:11:56
User entered '28 Sep 2020'	Atanas Filev (b) (4)	28 Sep 2020 14:58:27

US3952158

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:40:43

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User entered 'Sep 2020'	System	28 Sep 2020 14:58:27

US3952158

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:40:43

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User entered '2020'	System	28 Sep 2020 14:58:27

US3952158

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:40:43

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:11:56
User entered 'Amendment 3 (3)'	Atanas Filev (b) (4)	28 Sep 2020 14:58:27

US3952158

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:40:43

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:11:56
User entered 'Yes (Y)'	(b) (4) Atanas Filev (b) (4) (b) (4)	28 Sep 2020 14:58:27

US3952158

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:40:43

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:11:56
User entered empty.	Atanas Filev (b) (4)	28 Sep 2020 14:58:27

US3952158

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:40:43

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:11:56
User entered empty.	(b) (4) Atanas Filev (b) (4) (b) (4)	28 Sep 2020 14:58:27

US3952158

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:40:43

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:11:56
User entered 'No (N)'	(b) (4) Atanas Filev (b) (4) (b) (4)	28 Sep 2020 14:58:27

US3952158

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:40:43

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:11:56
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Sep 2020 13:22:51

US3952158

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:40:43

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User entered 'I'	System	28 Sep 2020 14:58:31

US3952158

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 12 Aug 2021 13:40:43

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:11:56
User entered 'Yes (Y)'	(b) (4) Atanas Filev (b) (4) (b) (4)	28 Sep 2020 14:58:31

US3952158

Folder: Screening

Form: Medical History Summary

Generated On: 12 Aug 2021 13:40:43

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:39:41

US3952158

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:40:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Oct 2020 06:10:11
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 02:57:32
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 14:40:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 14:40:58
Data point term sent to Coder	System	30 Sep 2020 14:40:27
User entered 'hypertension'	Nick Bart (b) (4)	30 Sep 2020 14:39:58

US3952158

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:40:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered 'un UNK 2011'	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:39:58

US3952158

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:40:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered '0'	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:39:58

US3952158

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:40:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
Query 'Per DM CLR: Please review response to 'Condition ongoing at study entry' = NO. Kindly note, this is a chronic condition and a stop date is unexpected, please verify status of this condition and consider updating response to Yes, as applicable. Else, clarify.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 05:26:04
User opened query 'Per DM CLR: Please review response to 'Condition ongoing at study entry' = NO. Kindly note, this is a chronic condition and a stop date is unexpected, please verify status of this condition and consider updating response to Yes, as applicable. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 02:57:03
User entered 'No (N)'	Nick Bart (b) (4)	30 Sep 2020 14:39:58

US3952158

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:40:43

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered 'un UNK 2011'	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:39:58

US3952158

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:40:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered '0'	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:39:58

US3952158

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:40:43

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User entered 'Jan 2011'	System	30 Sep 2020 14:39:58

US3952158

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:40:43

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User entered '2011'	System	30 Sep 2020 14:39:58

US3952158

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:40:43

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User entered 'Jan 2011'	System	30 Sep 2020 14:39:58

US3952158

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:40:43

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User entered '2011'	System	30 Sep 2020 14:39:58

US3952158

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:39:25

US3952158

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered '28 Sep 2020'	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:39:25

US3952158

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered '08:55'	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:39:25

US3952158

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User entered '28 Sep 2020 08:55'	System	30 Sep 2020 14:39:25

US3952158

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered '69.0' in	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:39:25
DataPoint set to visible.	System	28 Sep 2020 14:58:31

US3952158

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered '155.0' lb	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:39:25
DataPoint set to visible.	System	28 Sep 2020 14:58:31

US3952158

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User entered '22.93736'	System	30 Sep 2020 14:39:25
DataPoint set to visible.	System	28 Sep 2020 14:58:31

US3952158

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User entered 'kg/m2'	System	30 Sep 2020 14:39:25
DataPoint set to visible.	System	28 Sep 2020 14:58:31

US3952158

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:39:25

US3952158

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered empty.	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:39:25

US3952158

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered empty.	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:39:25

US3952158

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:39:25

US3952158

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User entered 'bpm'	System	30 Sep 2020 14:39:25

US3952158

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:39:25

US3952158

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User entered 'breaths/min'	System	30 Sep 2020 14:39:25

US3952158

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:39:25

US3952158

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User entered 'mmHg'	System	30 Sep 2020 14:39:25

US3952158

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:39:25

US3952158

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User entered 'mmHg'	System	30 Sep 2020 14:39:25

US3952158

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 18:33:26

US3952158

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26

US3952158

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:40:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:38:40

US3952158

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:40:43

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered '28 Sep 2020'	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:38:40

US3952158

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:40:43

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:38:32

US3952158

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:40:43

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:38:32

US3952158

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:40:43

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered 'No (N)'	Nick Bart (b) (4)	30 Sep 2020 14:38:32

US3952158

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:40:43

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered 'No (N)'	Nick Bart (b) (4)	30 Sep 2020 14:38:32

US3952158

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:40:43

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:38:32

US3952158

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:40:43

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered 'No (N)'	Nick Bart (b) (4)	30 Sep 2020 14:38:32

US3952158

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:40:43

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered 'No (N)'	Nick Bart (b) (4)	30 Sep 2020 14:38:32

US3952158

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:40:43

[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered 'No (N)'	Nick Bart (b) (4)	30 Sep 2020 14:38:32

US3952158

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:40:43

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:38:32

US3952158

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:40:43

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered 'No (N)'	Nick Bart (b) (4)	30 Sep 2020 14:38:32

US3952158

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:40:43

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered 'No (N)'	Nick Bart (b) (4)	30 Sep 2020 14:38:32

US3952158

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:40:43

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:38:32

US3952158

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:40:43

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered 'actively working roofer'	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:38:32

US3952158

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:40:43

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered '0'	Nick Bart (b) (4)	30 Sep 2020 14:38:32

US3952158

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:40:43

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered '0'	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:38:32

US3952158

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:40:43

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered '0'	Nick Bart (b) (4)	30 Sep 2020 14:38:32

US3952158

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:40:43

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered '0'	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:38:32

US3952158

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:40:43

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered '0'	Nick Bart (b) (4)	30 Sep 2020 14:38:32

US3952158

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:40:43

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered 'I'	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:38:32

US3952158

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:40:43

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered '0'	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:38:32

US3952158

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:40:43

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:33:26
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered empty.	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:38:32

US3952158

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:40:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:40:11

US3952158

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:40:43

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered '28 Sep 2020'	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:40:11

US3952158

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:40:43

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered 'Clinic (Clinic)'	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:40:11

US3952158

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:40:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User entered 'VISIT1'	System	30 Sep 2020 14:40:11

US3952158

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:40:43

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered '28 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Sep 2020 13:42:39

US3952158

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:40:43

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered '115687'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Sep 2020 13:42:39

US3952158

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:40:43

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Sep 2020 13:42:39

US3952158

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:40:43

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:40:29

US3952158

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:40:43

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:40:29

US3952158

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:40:43

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:40:29

US3952158

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:40:43

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:40:29

US3952158

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:40:43

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:40:29

US3952158

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:40:43

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:40:29
DataPoint set to visible.	System	28 Sep 2020 14:58:27

US3952158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:40:43

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:42:43

US3952158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:40:43

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:42:43

US3952158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:40:43

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:42:43

US3952158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:40:43

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:42:43

US3952158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User accepted default value 'Pre-Dose (PREDOSE)'	Nick Bart (b) (4)	30 Sep 2020 14:42:43

US3952158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:42:43

US3952158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered '28 Sep 2020'	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:42:43

US3952158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:43

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered '08:55'	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:42:43

US3952158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User entered '28 Sep 2020 08:55'	System	30 Sep 2020 14:42:43

US3952158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:43

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered '37.1' C	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:42:43

US3952158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered 'Oral (Oral)'	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:42:43

US3952158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered empty.	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:42:43

US3952158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered '97'	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:42:43

US3952158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User entered 'bpm'	System	30 Sep 2020 14:42:43

US3952158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered '16'	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:42:43

US3952158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User entered 'breaths/min'	System	30 Sep 2020 14:42:43

US3952158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User closed query 'Per CDM: Per CCG V2.0 page 53, SBP \leq 89 or \geq 141 mmHg is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you ' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 06:29:27
Query 'Per CDM: Per CCG V2.0 page 53, SBP \leq 89 or \geq 141 mmHg is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you ' answered with 'NCS' (Site from DM).	Nick Bart (b) (4)	29 Dec 2020 15:11:49
User opened query 'Per CDM: Per CCG V2.0 page 53, SBP \leq 89 or \geq 141 mmHg is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you ' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 12:23:29
User entered '150'	Nick Bart (b) (4)	30 Sep 2020 14:42:43

US3952158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User entered 'mmHg'	System	30 Sep 2020 14:42:43

US3952158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User closed query 'Per CDM: Per CCG V2.0 page 50, DBP \geq 91 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Dec 2020 12:23:11
Query 'Per CDM: Per CCG V2.0 page 50, DBP \geq 91 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you.' answered with 'NCS' (Site from DM).	Nick Bart (b) (4)	23 Dec 2020 16:39:21
User opened query 'Per CDM: Per CCG V2.0 page 50, DBP \geq 91 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 08:31:49
User entered '102'	Nick Bart (b) (4)	30 Sep 2020 14:42:43

US3952158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:43

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User entered 'mmHg'	System	30 Sep 2020 14:42:43

US3952158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:40:43

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:42:43

US3952158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:40:43

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:42:43

US3952158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User accepted default value 'Post-Dose (POSTDOSE)'	Nick Bart (b) (4)	30 Sep 2020 14:42:43

US3952158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:42:43

US3952158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered '28 Sep 2020'	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:42:43

US3952158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:43

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered '11:11'	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:42:43

US3952158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User entered '28 Sep 2020 11:11'	System	30 Sep 2020 14:42:43

US3952158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:43

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered '36.8' C	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:42:43

US3952158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered 'Oral (Oral)'	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:42:43

US3952158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered empty.	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:42:43

US3952158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered '81'	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:42:43

US3952158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User entered 'bpm'	System	30 Sep 2020 14:42:43

US3952158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered '12'	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:42:43

US3952158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User entered 'breaths/min'	System	30 Sep 2020 14:42:43

US3952158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:43

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered '129'	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:42:43

US3952158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User entered 'mmHg'	System	30 Sep 2020 14:42:43

US3952158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:43

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered '87'	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:42:43

US3952158

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User entered 'mmHg'	System	30 Sep 2020 14:42:43

US3952158

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:40:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:40:20

US3952158

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:40:43

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered empty.	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:40:20

US3952158

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:40:43

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered 'Yes (Y)'	(b) (4) Atanas Filev (b) (4) (b) (4)	28 Sep 2020 15:00:21

US3952158

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:40:43

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered empty.	(b) (4) Atanas Filev (b) (4) (b) (4)	28 Sep 2020 15:00:21

US3952158

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:40:43

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered empty.	(b) (4) Atanas Filev (b) (4) (b) (4)	28 Sep 2020 15:00:21

US3952158

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:40:43

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User entered 'MRNA-1273 OR PLACEBO'	System	28 Sep 2020 15:00:21

US3952158

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:40:43

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered '28 Sep 2020'	(b) (4) Atanas Filev (b) (4) (b) (4)	28 Sep 2020 15:00:21

US3952158

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:40:43

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered '10:35'	(b) (4) Atanas Filev (b) (4) (b) (4)	28 Sep 2020 15:00:21

US3952158

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:40:43

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User entered '28 Sep 2020 10:35'	System	28 Sep 2020 15:00:21

US3952158

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:40:43

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered 'Left Arm (LEFT ARM)'	(b) (4) Atanas Filev (b) (4) (b) (4)	28 Sep 2020 15:00:21

US3952158

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:40:43

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User entered 'ONCE'	System	28 Sep 2020 15:00:21

US3952158

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:40:43

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User entered 'INTRAMUSCULAR'	System	28 Sep 2020 15:00:21

US3952158

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:40:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:42:58

US3952158

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:40:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered '28 Sep 2020'	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:42:58

US3952158

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:40:43

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered '09:50'	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:42:58

US3952158

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:40:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User entered '28 Sep 2020 09:50'	System	30 Sep 2020 14:42:58

US3952158

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:40:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered '28 Sep 2020'	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:43:16

US3952158

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:40:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Nick Bart (b) (4)	30 Sep 2020 14:43:16

US3952158

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:40:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:43:16

US3952158

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:40:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered '09:44'	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:43:16

US3952158

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:40:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User entered '28 Sep 2020 09:44'	System	30 Sep 2020 14:43:16

US3952158

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:40:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Nick Bart (b) (4)	30 Sep 2020 14:43:16

US3952158

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:40:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:43:16

US3952158

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:40:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered empty.	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:43:16

US3952158

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:40:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User entered empty.	System	30 Sep 2020 14:43:16

US3952158

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:40:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	30 Sep 2020 14:40:17

US3952158

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:40:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User entered '1'	System	30 Sep 2020 14:40:17

US3952158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
Data entry locked.	System	28 Sep 2020 15:00:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:40:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-28T11:13:13', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'a3e1601a-8749-4fdd-adaf-29c0e05fbbc8'	System	28 Sep 2020 15:13:43
User entered 'Yes (Y)'	System	28 Sep 2020 15:13:43

US3952158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:40:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-28T11:13:26', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'a3e1601a-8749-4fdd-adaf-29c0e05fbbc8' User entered '98.3'	System	28 Sep 2020 15:13:43
	System	28 Sep 2020 15:13:43

US3952158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:40:43

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-28T11:13:34', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'a3e1601a-8749-4fdd-adaf-29c0e05fbbc8'	System	28 Sep 2020 15:13:43
User entered 'No (N)'	System	28 Sep 2020 15:13:43

US3952158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:40:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-28T11:13:40', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'a3e1601a-8749-4fdd-adaf-29c0e05fbbc8'	System	28 Sep 2020 15:13:43
User entered '28 Sep 2020 11:13'	System	28 Sep 2020 15:13:43

US3952158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:40:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
User entered '28 Sep 2020 10:55'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:40:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
User entered '28 Sep 2020 13:25'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
Data entry locked.	System	28 Sep 2020 15:00:21
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:40:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-28T16:58:01', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'cadd7c74-bb5b-4895-b5d8-5705676b5640'	System	28 Sep 2020 20:58:30
User entered 'Yes (Y)'	System	28 Sep 2020 20:58:30

US3952158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:40:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-28T16:58:10', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'cadd7c74-bb5b-4895-b5d8-5705676b5640'	System	28 Sep 2020 20:58:30
User entered '98.7'	System	28 Sep 2020 20:58:30

US3952158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:40:43

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-28T16:58:17', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'cadd7c74-bb5b-4895-b5d8-5705676b5640'	System	28 Sep 2020 20:58:30
User entered 'No (N)'	System	28 Sep 2020 20:58:30

US3952158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:40:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-28T16:58:26', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'cadd7c74-bb5b-4895-b5d8-5705676b5640'	System	28 Sep 2020 20:58:30
User entered '28 Sep 2020 16:58'	System	28 Sep 2020 20:58:30

US3952158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:40:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
User entered '28 Sep 2020 14:20'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:40:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
Data entry locked.	System	28 Sep 2020 15:00:21
User entered 'Day 2'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:40:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-29T14:16:38', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'cec7ce7f-c24c-423f-82ef-ec51b6aef96c'	System	29 Sep 2020 18:16:56
User entered 'Yes (Y)'	System	29 Sep 2020 18:16:56

US3952158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:40:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-29T14:16:44', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'cec7ce7f-c24c-423f-82ef-ec51b6aef96c'	System	29 Sep 2020 18:16:56
User entered '97.8'	System	29 Sep 2020 18:16:56

US3952158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:40:43

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-29T14:16:47', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'cec7ce7f-c24c-423f-82ef-ec51b6aef96c'	System	29 Sep 2020 18:16:56
User entered 'No (N)'	System	29 Sep 2020 18:16:56

US3952158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:40:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-29T14:16:51', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'cec7ce7f-c24c-423f-82ef-ec51b6aef96c'	System	29 Sep 2020 18:16:56
User entered '29 Sep 2020 14:16'	System	29 Sep 2020 18:16:56

US3952158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:40:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:40:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
Data entry locked.	System	28 Sep 2020 15:00:21
User entered 'Day 3'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:40:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-30T12:14:11', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'c9fc68ba-17ba-4e0e-b0ec-aac5585302f0'	System	30 Sep 2020 16:14:24
User entered 'Yes (Y)'	System	30 Sep 2020 16:14:24

US3952158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:40:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-30T12:14:16', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'c9fc68ba-17ba-4e0e-b0ec-aac5585302f0'	System	30 Sep 2020 16:14:24
User entered '97.5'	System	30 Sep 2020 16:14:24

US3952158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:40:43

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-30T12:14:19', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'c9fc68ba-17ba-4e0e-b0ec-aac5585302f0'	System	30 Sep 2020 16:14:24
User entered 'No (N)'	System	30 Sep 2020 16:14:24

US3952158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:40:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-30T12:14:22', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'c9fc68ba-17ba-4e0e-b0ec-aac5585302f0'	System	30 Sep 2020 16:14:24
User entered '30 Sep 2020 12:14'	System	30 Sep 2020 16:14:24

US3952158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:40:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:40:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
Data entry locked.	System	28 Sep 2020 15:00:21
User entered 'Day 4'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:40:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-01T13:38:45', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'cc8dfbdb-1baa-4b35-9ac7-4ef6c03e35e3'	System	01 Oct 2020 17:38:58
User entered 'Yes (Y)'	System	01 Oct 2020 17:38:58

US3952158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:40:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-01T13:38:50', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'cc8dfbdb-1baa-4b35-9ac7-4ef6c03e35e3'	System	01 Oct 2020 17:38:58
User entered '98.8'	System	01 Oct 2020 17:38:58

US3952158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:40:43

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-01T13:38:52', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'cc8dfbdb-1baa-4b35-9ac7-4ef6c03e35e3'	System	01 Oct 2020 17:38:58
User entered 'No (N)'	System	01 Oct 2020 17:38:58

US3952158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:40:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-01T13:38:56', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'cc8dfbdb-1baa-4b35-9ac7-4ef6c03e35e3'	System	01 Oct 2020 17:38:58
User entered '01 Oct 2020 13:38'	System	01 Oct 2020 17:38:58

US3952158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:40:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:40:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
Data entry locked.	System	28 Sep 2020 15:00:21
User entered 'Day 5'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:40:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-02T17:19:52', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'abf746bd-cad9-45b8-abf3-3ace432fc693'	System	02 Oct 2020 21:20:12
User entered 'Yes (Y)'	System	02 Oct 2020 21:20:12

US3952158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:40:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-02T17:19:59', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'abf746bd-cad9-45b8-abf3-3ace432fc693'	System	02 Oct 2020 21:20:12
User entered '98.6'	System	02 Oct 2020 21:20:12

US3952158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:40:43

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-02T17:20:03', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'abf746bd-cad9-45b8-abf3-3ace432fc693'	System	02 Oct 2020 21:20:12
User entered 'No (N)'	System	02 Oct 2020 21:20:12

US3952158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:40:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-02T17:20:07', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'abf746bd-cad9-45b8-abf3-3ace432fc693'	System	02 Oct 2020 21:20:12
User entered '02 Oct 2020 17:20'	System	02 Oct 2020 21:20:12

US3952158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:40:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:40:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
Data entry locked.	System	28 Sep 2020 15:00:21
User entered 'Day 6'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:40:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-03T17:31:48', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'd2222f29-b04c-4ccc-b084-5ae2d3febd92'	System	03 Oct 2020 21:32:40
User entered 'Yes (Y)'	System	03 Oct 2020 21:32:40

US3952158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:40:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-03T17:32:30', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'd2222f29-b04c-4ccc-b084-5ae2d3febd92'	System	03 Oct 2020 21:32:40
User entered '98.5'	System	03 Oct 2020 21:32:40

US3952158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:40:43

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-03T17:32:34', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'd2222f29-b04c-4ccc-b084-5ae2d3febd92'	System	03 Oct 2020 21:32:40
User entered 'No (N)'	System	03 Oct 2020 21:32:40

US3952158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:40:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-03T17:32:38', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'd2222f29-b04c-4ccc-b084-5ae2d3febd92'	System	03 Oct 2020 21:32:40
User entered '03 Oct 2020 17:32'	System	03 Oct 2020 21:32:40

US3952158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:40:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:40:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
Data entry locked.	System	28 Sep 2020 15:00:21
User entered 'Day 7'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:40:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-04T18:31:59', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'c16d3c94-4762-4e49-870c-2a543bf56fbd'	System	04 Oct 2020 22:32:19
User entered 'Yes (Y)'	System	04 Oct 2020 22:32:19

US3952158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:40:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-04T18:32:05', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'c16d3c94-4762-4e49-870c-2a543bf56fbd'	System	04 Oct 2020 22:32:19
User entered '97.9'	System	04 Oct 2020 22:32:19

US3952158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:40:43

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-04T18:32:09', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'c16d3c94-4762-4e49-870c-2a543bf56fbd'	System	04 Oct 2020 22:32:19
User entered 'No (N)'	System	04 Oct 2020 22:32:19

US3952158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:40:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-04T18:32:14', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'c16d3c94-4762-4e49-870c-2a543bf56fbd'	System	04 Oct 2020 22:32:19
User entered '04 Oct 2020 18:32'	System	04 Oct 2020 22:32:19

US3952158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:40:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:40:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
Data entry locked.	System	28 Sep 2020 15:00:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:40:43

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-28T11:15:27', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'c1cae1d7-f945-4c32-b8c1-9ff7973a024e'	System	28 Sep 2020 15:18:07
User entered 'None (1)'	System	28 Sep 2020 15:18:07

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:40:43

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-28T11:16:11', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'c1cae1d7-f945-4c32-b8c1-9ff7973a024e'	System	28 Sep 2020 15:18:07
User entered 'No (N)'	System	28 Sep 2020 15:18:07

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:40:43

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-28T11:17:21', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'c1cae1d7-f945-4c32-b8c1-9ff7973a024e'	System	28 Sep 2020 15:18:07
User entered 'No (N)'	System	28 Sep 2020 15:18:07

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:40:43

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-28T11:17:55', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'c1cae1d7-f945-4c32-b8c1-9ff7973a024e'	System	28 Sep 2020 15:18:07
User entered 'None (1)'	System	28 Sep 2020 15:18:07

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:40:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-28T11:18:00', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'c1cae1d7-f945-4c32-b8c1-9ff7973a024e'	System	28 Sep 2020 15:18:07
User entered '28 Sep 2020 11:18'	System	28 Sep 2020 15:18:07

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:40:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
User entered '28 Sep 2020 10:55'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:40:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
User entered '28 Sep 2020 13:25'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
Data entry locked.	System	28 Sep 2020 15:00:21
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:40:43

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-28T16:58:45', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'a74eb84d-afb6-4c9e-b52b-bcf142a382ed'	System	28 Sep 2020 20:59:36
User entered 'None (1)'	System	28 Sep 2020 20:59:36

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:40:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-28T16:58:57', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'a74eb84d-afb6-4c9e-b52b-bcf142a382ed'	System	28 Sep 2020 20:59:36
User entered 'No (N)'	System	28 Sep 2020 20:59:36

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:40:43

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-28T16:59:08', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'a74eb84d-afb6-4c9e-b52b-bcf142a382ed'	System	28 Sep 2020 20:59:36
User entered 'No (N)'	System	28 Sep 2020 20:59:36

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:40:43

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-28T16:59:29', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'a74eb84d-afb6-4c9e-b52b-bcf142a382ed'	System	28 Sep 2020 20:59:36
User entered 'None (1)'	System	28 Sep 2020 20:59:36

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:40:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-28T16:59:33', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'a74eb84d-afb6-4c9e-b52b-bcf142a382ed'	System	28 Sep 2020 20:59:36
User entered '28 Sep 2020 16:59'	System	28 Sep 2020 20:59:36

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:40:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
User entered '28 Sep 2020 14:20'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:40:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
Data entry locked.	System	28 Sep 2020 15:00:21
User entered 'Day 2'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:40:43

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-29T14:16:58', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'b0b98848-f271-41b9-8eee-fd9de055c11a'	System	29 Sep 2020 18:17:14
User entered 'None (1)'	System	29 Sep 2020 18:17:14

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:40:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-29T14:17:01', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'b0b98848-f271-41b9-8eee-fd9de055c11a'	System	29 Sep 2020 18:17:14
User entered 'No (N)'	System	29 Sep 2020 18:17:14

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:40:43

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-29T14:17:04', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'b0b98848-f271-41b9-8eee-fd9de055c11a'	System	29 Sep 2020 18:17:14
User entered 'No (N)'	System	29 Sep 2020 18:17:14

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:40:43

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-29T14:17:07', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'b0b98848-f271-41b9-8eee-fd9de055c11a'	System	29 Sep 2020 18:17:14
User entered 'None (1)'	System	29 Sep 2020 18:17:14

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:40:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-29T14:17:09', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'b0b98848-f271-41b9-8eee-fd9de055c11a'	System	29 Sep 2020 18:17:14
User entered '29 Sep 2020 14:17'	System	29 Sep 2020 18:17:14

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:40:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:40:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
Data entry locked.	System	28 Sep 2020 15:00:21
User entered 'Day 3'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:40:43

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-30T12:14:28', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '19b1cc46-fda1-4af5-b96d-98e9b4e92a82'	System	30 Sep 2020 16:14:42
User entered 'None (1)'	System	30 Sep 2020 16:14:42

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:40:43

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-30T12:14:31', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '19b1cc46-fda1-4af5-b96d-98e9b4e92a82'	System	30 Sep 2020 16:14:42
User entered 'No (N)'	System	30 Sep 2020 16:14:42

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:40:43

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-30T12:14:34', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '19b1cc46-fda1-4af5-b96d-98e9b4e92a82'	System	30 Sep 2020 16:14:42
User entered 'No (N)'	System	30 Sep 2020 16:14:42

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:40:43

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-30T12:14:36', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '19b1cc46-fda1-4af5-b96d-98e9b4e92a82'	System	30 Sep 2020 16:14:42
User entered 'None (1)'	System	30 Sep 2020 16:14:42

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:40:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-30T12:14:39', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '19b1cc46-fda1-4af5-b96d-98e9b4e92a82'	System	30 Sep 2020 16:14:42
User entered '30 Sep 2020 12:14'	System	30 Sep 2020 16:14:42

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:40:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:40:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
Data entry locked.	System	28 Sep 2020 15:00:21
User entered 'Day 4'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:40:43

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-01T13:39:01', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '3d233275-c842-4d4f-8872-785d98919d11'	System	01 Oct 2020 17:39:15
User entered 'None (1)'	System	01 Oct 2020 17:39:15

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:40:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-01T13:39:03', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '3d233275-c842-4d4f-8872-785d98919d11'	System	01 Oct 2020 17:39:15
User entered 'No (N)'	System	01 Oct 2020 17:39:15

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:40:43

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-01T13:39:08', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '3d233275-c842-4d4f-8872-785d98919d11'	System	01 Oct 2020 17:39:15
User entered 'No (N)'	System	01 Oct 2020 17:39:15

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:40:43

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-01T13:39:10', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '3d233275-c842-4d4f-8872-785d98919d11'	System	01 Oct 2020 17:39:15
User entered 'None (1)'	System	01 Oct 2020 17:39:15

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:40:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-01T13:39:13', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '3d233275-c842-4d4f-8872-785d98919d11'	System	01 Oct 2020 17:39:15
User entered '01 Oct 2020 13:39'	System	01 Oct 2020 17:39:15

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:40:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:40:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
Data entry locked.	System	28 Sep 2020 15:00:21
User entered 'Day 5'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:40:43

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-02T17:20:16', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'f4343e3e-3ed9-4503-bdb9-8c5ad49fa277'	System	02 Oct 2020 21:20:59
User entered 'None (1)'	System	02 Oct 2020 21:20:59

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:40:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-02T17:20:20', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'f4343e3e-3ed9-4503-bdb9-8c5ad49fa277'	System	02 Oct 2020 21:20:59
User entered 'No (N)'	System	02 Oct 2020 21:20:59

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:40:43

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-02T17:20:46', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'f4343e3e-3ed9-4503-bdb9-8c5ad49fa277'	System	02 Oct 2020 21:20:59
User entered 'No (N)'	System	02 Oct 2020 21:20:59

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:40:43

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-02T17:20:52', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'f4343e3e-3ed9-4503-bdb9-8c5ad49fa277'	System	02 Oct 2020 21:20:59
User entered 'None (1)'	System	02 Oct 2020 21:20:59

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:40:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-02T17:20:55', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'f4343e3e-3ed9-4503-bdb9-8c5ad49fa277'	System	02 Oct 2020 21:20:59
User entered '02 Oct 2020 17:20'	System	02 Oct 2020 21:20:59

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:40:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:40:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
Data entry locked.	System	28 Sep 2020 15:00:21
User entered 'Day 6'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:40:43

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-03T17:32:43', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'f680e965-ab19-4069-b764-8aaa04cf6505'	System	03 Oct 2020 21:32:56
User entered 'None (1)'	System	03 Oct 2020 21:32:56

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:40:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-03T17:32:46', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'f680e965-ab19-4069-b764-8aaa04cf6505'	System	03 Oct 2020 21:32:56
User entered 'No (N)'	System	03 Oct 2020 21:32:56

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:40:43

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-03T17:32:47', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'f680e965-ab19-4069-b764-8aaa04cf6505'	System	03 Oct 2020 21:32:56
User entered 'No (N)'	System	03 Oct 2020 21:32:56

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:40:43

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-03T17:32:50', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'f680e965-ab19-4069-b764-8aaa04cf6505'	System	03 Oct 2020 21:32:56
User entered 'None (1)'	System	03 Oct 2020 21:32:56

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:40:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-03T17:32:52', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'f680e965-ab19-4069-b764-8aaa04cf6505'	System	03 Oct 2020 21:32:56
User entered '03 Oct 2020 17:32'	System	03 Oct 2020 21:32:56

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:40:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:40:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
Data entry locked.	System	28 Sep 2020 15:00:21
User entered 'Day 7'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:40:43

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-04T18:32:20', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '47b172c2-4445-4d3d-a81e-ee229e2c195c'	System	04 Oct 2020 22:32:31
User entered 'None (1)'	System	04 Oct 2020 22:32:31

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:40:43

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-04T18:32:22', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '47b172c2-4445-4d3d-a81e-ee229e2c195c'	System	04 Oct 2020 22:32:31
User entered 'No (N)'	System	04 Oct 2020 22:32:31

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:40:43

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-04T18:32:24', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '47b172c2-4445-4d3d-a81e-ee229e2c195c'	System	04 Oct 2020 22:32:31
User entered 'No (N)'	System	04 Oct 2020 22:32:31

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:40:43

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-04T18:32:26', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '47b172c2-4445-4d3d-a81e-ee229e2c195c'	System	04 Oct 2020 22:32:31
User entered 'None (1)'	System	04 Oct 2020 22:32:31

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:40:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-04T18:32:29', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '47b172c2-4445-4d3d-a81e-ee229e2c195c'	System	04 Oct 2020 22:32:31
User entered '04 Oct 2020 18:32'	System	04 Oct 2020 22:32:31

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:40:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:40:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
Data entry locked.	System	28 Sep 2020 15:00:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:40:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-28T11:18:11', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '0a1f13ae-2071-4b62-9d09-36c5336d0d47'	System	28 Sep 2020 15:19:11
User entered 'None (0)'	System	28 Sep 2020 15:19:11

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:40:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-28T11:18:31', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '0a1f13ae-2071-4b62-9d09-36c5336d0d47'	System	28 Sep 2020 15:19:11
User entered 'None (0)'	System	28 Sep 2020 15:19:11

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:40:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-28T11:18:37', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '0a1f13ae-2071-4b62-9d09-36c5336d0d47'	System	28 Sep 2020 15:19:11
User entered 'None (0)'	System	28 Sep 2020 15:19:11

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:40:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-28T11:18:42', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '0a1f13ae-2071-4b62-9d09-36c5336d0d47'	System	28 Sep 2020 15:19:11
User entered 'None (0)'	System	28 Sep 2020 15:19:11

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:40:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-28T11:18:45', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '0a1f13ae-2071-4b62-9d09-36c5336d0d47'	System	28 Sep 2020 15:19:11
User entered 'None (0)'	System	28 Sep 2020 15:19:11

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:40:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-28T11:18:48', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '0a1f13ae-2071-4b62-9d09-36c5336d0d47'	System	28 Sep 2020 15:19:11
User entered 'None (0)'	System	28 Sep 2020 15:19:11

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:40:43

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-28T11:19:03', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '0a1f13ae-2071-4b62-9d09-36c5336d0d47'	System	28 Sep 2020 15:19:11
User entered 'No (N)'	System	28 Sep 2020 15:19:11

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:40:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-28T11:19:07', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '0a1f13ae-2071-4b62-9d09-36c5336d0d47'	System	28 Sep 2020 15:19:11
User entered '28 Sep 2020 11:19'	System	28 Sep 2020 15:19:11

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:40:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
User entered '28 Sep 2020 10:55'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:40:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
User entered '28 Sep 2020 13:25'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
Data entry locked.	System	28 Sep 2020 15:00:21
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:40:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-28T16:59:46', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '2a665de0-a3ce-4d8c-b19b-560b94ef9469'	System	28 Sep 2020 21:00:15
User entered 'None (0)'	System	28 Sep 2020 21:00:15

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:40:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-28T16:59:48', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '2a665de0-a3ce-4d8c-b19b-560b94ef9469'	System	28 Sep 2020 21:00:15
User entered 'None (0)'	System	28 Sep 2020 21:00:15

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:40:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-28T16:59:52', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '2a665de0-a3ce-4d8c-b19b-560b94ef9469'	System	28 Sep 2020 21:00:15
User entered 'None (0)'	System	28 Sep 2020 21:00:15

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:40:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-28T16:59:55', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '2a665de0-a3ce-4d8c-b19b-560b94ef9469'	System	28 Sep 2020 21:00:15
User entered 'None (0)'	System	28 Sep 2020 21:00:15

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:40:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-28T16:59:58', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '2a665de0-a3ce-4d8c-b19b-560b94ef9469'	System	28 Sep 2020 21:00:15
User entered 'None (0)'	System	28 Sep 2020 21:00:15

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:40:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-28T17:00:00', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '2a665de0-a3ce-4d8c-b19b-560b94ef9469'	System	28 Sep 2020 21:00:15
User entered 'None (0)'	System	28 Sep 2020 21:00:15

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:40:43

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-28T17:00:06', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '2a665de0-a3ce-4d8c-b19b-560b94ef9469'	System	28 Sep 2020 21:00:15
User entered 'No (N)'	System	28 Sep 2020 21:00:15

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:40:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-28T17:00:10', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '2a665de0-a3ce-4d8c-b19b-560b94ef9469'	System	28 Sep 2020 21:00:15
User entered '28 Sep 2020 17:00'	System	28 Sep 2020 21:00:15

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:40:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
User entered '28 Sep 2020 14:20'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:40:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
Data entry locked.	System	28 Sep 2020 15:00:21
User entered 'Day 2'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:40:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-29T14:17:14', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '0ef3d00c-8eb3-42dc-8f5c-59fc9a234d1b'	System	29 Sep 2020 18:17:38
User entered 'None (0)'	System	29 Sep 2020 18:17:38

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:40:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-29T14:17:17', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '0ef3d00c-8eb3-42dc-8f5c-59fc9a234d1b'	System	29 Sep 2020 18:17:38
User entered 'None (0)'	System	29 Sep 2020 18:17:38

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:40:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-29T14:17:20', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '0ef3d00c-8eb3-42dc-8f5c-59fc9a234d1b'	System	29 Sep 2020 18:17:38
User entered 'None (0)'	System	29 Sep 2020 18:17:38

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:40:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-29T14:17:22', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '0ef3d00c-8eb3-42dc-8f5c-59fc9a234d1b'	System	29 Sep 2020 18:17:38
User entered 'None (0)'	System	29 Sep 2020 18:17:38

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:40:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-29T14:17:24', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '0ef3d00c-8eb3-42dc-8f5c-59fc9a234d1b'	System	29 Sep 2020 18:17:38
User entered 'None (0)'	System	29 Sep 2020 18:17:38

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:40:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-29T14:17:26', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '0ef3d00c-8eb3-42dc-8f5c-59fc9a234d1b'	System	29 Sep 2020 18:17:38
User entered 'None (0)'	System	29 Sep 2020 18:17:38

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:40:43

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-29T14:17:30', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '0ef3d00c-8eb3-42dc-8f5c-59fc9a234d1b'	System	29 Sep 2020 18:17:38
User entered 'No (N)'	System	29 Sep 2020 18:17:38

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:40:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-29T14:17:32', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '0ef3d00c-8eb3-42dc-8f5c-59fc9a234d1b'	System	29 Sep 2020 18:17:38
User entered '29 Sep 2020 14:17'	System	29 Sep 2020 18:17:38

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:40:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:40:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
Data entry locked.	System	28 Sep 2020 15:00:21
User entered 'Day 3'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:40:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-30T12:14:44', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '8d6e03b8-04e0-4a20-abd3-bff27abe7746'	System	30 Sep 2020 16:15:10
User entered 'None (0)'	System	30 Sep 2020 16:15:10

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:40:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-30T12:14:47', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '8d6e03b8-04e0-4a20-abd3-bff27abe7746'	System	30 Sep 2020 16:15:10
User entered 'None (0)'	System	30 Sep 2020 16:15:10

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:40:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-30T12:14:49', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '8d6e03b8-04e0-4a20-abd3-bff27abe7746'	System	30 Sep 2020 16:15:10
User entered 'None (0)'	System	30 Sep 2020 16:15:10

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:40:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-30T12:14:51', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '8d6e03b8-04e0-4a20-abd3-bff27abe7746'	System	30 Sep 2020 16:15:10
User entered 'None (0)'	System	30 Sep 2020 16:15:10

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:40:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-30T12:14:53', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '8d6e03b8-04e0-4a20-abd3-bff27abe7746'	System	30 Sep 2020 16:15:10
User entered 'None (0)'	System	30 Sep 2020 16:15:10

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:40:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-30T12:14:57', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '8d6e03b8-04e0-4a20-abd3-bff27abe7746'	System	30 Sep 2020 16:15:10
User entered 'None (0)'	System	30 Sep 2020 16:15:10

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:40:43

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-30T12:15:04', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '8d6e03b8-04e0-4a20-abd3-bff27abe7746'	System	30 Sep 2020 16:15:10
User entered 'No (N)'	System	30 Sep 2020 16:15:10

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:40:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-09-30T12:15:06', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '8d6e03b8-04e0-4a20-abd3-bff27abe7746'	System	30 Sep 2020 16:15:10
User entered '30 Sep 2020 12:15'	System	30 Sep 2020 16:15:10

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:40:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:40:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
Data entry locked.	System	28 Sep 2020 15:00:21
User entered 'Day 4'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:40:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-01T13:39:17', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'e430b41c-699d-4551-b9c7-2c5b3bc03178'	System	01 Oct 2020 17:39:36
User entered 'None (0)'	System	01 Oct 2020 17:39:36

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:40:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-01T13:39:18', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'e430b41c-699d-4551-b9c7-2c5b3bc03178'	System	01 Oct 2020 17:39:36
User entered 'None (0)'	System	01 Oct 2020 17:39:36

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:40:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-01T13:39:20', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'e430b41c-699d-4551-b9c7-2c5b3bc03178'	System	01 Oct 2020 17:39:36
User entered 'None (0)'	System	01 Oct 2020 17:39:36

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:40:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-01T13:39:22', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'e430b41c-699d-4551-b9c7-2c5b3bc03178'	System	01 Oct 2020 17:39:36
User entered 'None (0)'	System	01 Oct 2020 17:39:36

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:40:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-01T13:39:24', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'e430b41c-699d-4551-b9c7-2c5b3bc03178'	System	01 Oct 2020 17:39:36
User entered 'None (0)'	System	01 Oct 2020 17:39:36

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:40:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-01T13:39:26', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'e430b41c-699d-4551-b9c7-2c5b3bc03178'	System	01 Oct 2020 17:39:36
User entered 'None (0)'	System	01 Oct 2020 17:39:36

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:40:43

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-01T13:39:30', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'e430b41c-699d-4551-b9c7-2c5b3bc03178'	System	01 Oct 2020 17:39:36
User entered 'No (N)'	System	01 Oct 2020 17:39:36

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:40:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-01T13:39:33', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'e430b41c-699d-4551-b9c7-2c5b3bc03178'	System	01 Oct 2020 17:39:36
User entered '01 Oct 2020 13:39'	System	01 Oct 2020 17:39:36

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:40:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:40:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
Data entry locked.	System	28 Sep 2020 15:00:21
User entered 'Day 5'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:40:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-02T17:21:12', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '4ae96140-fc7e-4bbc-baf3-2c1a83b57c79'	System	02 Oct 2020 21:21:36
User entered 'None (0)'	System	02 Oct 2020 21:21:36

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:40:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-02T17:21:14', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '4ae96140-fc7e-4bbc-baf3-2c1a83b57c79'	System	02 Oct 2020 21:21:36
User entered 'None (0)'	System	02 Oct 2020 21:21:36

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:40:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-02T17:21:16', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '4ae96140-fc7e-4bbc-baf3-2c1a83b57c79'	System	02 Oct 2020 21:21:36
User entered 'None (0)'	System	02 Oct 2020 21:21:36

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:40:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-02T17:21:18', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '4ae96140-fc7e-4bbc-baf3-2c1a83b57c79'	System	02 Oct 2020 21:21:36
User entered 'None (0)'	System	02 Oct 2020 21:21:36

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:40:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-02T17:21:21', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '4ae96140-fc7e-4bbc-baf3-2c1a83b57c79'	System	02 Oct 2020 21:21:36
User entered 'None (0)'	System	02 Oct 2020 21:21:36

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:40:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-02T17:21:23', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '4ae96140-fc7e-4bbc-baf3-2c1a83b57c79'	System	02 Oct 2020 21:21:36
User entered 'None (0)'	System	02 Oct 2020 21:21:36

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:40:43

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-02T17:21:29', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '4ae96140-fc7e-4bbc-baf3-2c1a83b57c79'	System	02 Oct 2020 21:21:36
User entered 'No (N)'	System	02 Oct 2020 21:21:36

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:40:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-02T17:21:31', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '4ae96140-fc7e-4bbc-baf3-2c1a83b57c79'	System	02 Oct 2020 21:21:36
User entered '02 Oct 2020 17:21'	System	02 Oct 2020 21:21:36

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:40:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:40:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
Data entry locked.	System	28 Sep 2020 15:00:21
User entered 'Day 6'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:40:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-03T17:32:57', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'fac8a870-7b41-4861-9dce-8a311a095ba6'	System	03 Oct 2020 21:33:19
User entered 'None (0)'	System	03 Oct 2020 21:33:19

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:40:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-03T17:32:59', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'fac8a870-7b41-4861-9dce-8a311a095ba6'	System	03 Oct 2020 21:33:19
User entered 'None (0)'	System	03 Oct 2020 21:33:19

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:40:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-03T17:33:01', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'fac8a870-7b41-4861-9dce-8a311a095ba6'	System	03 Oct 2020 21:33:19
User entered 'None (0)'	System	03 Oct 2020 21:33:19

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:40:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-03T17:33:03', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'fac8a870-7b41-4861-9dce-8a311a095ba6'	System	03 Oct 2020 21:33:19
User entered 'None (0)'	System	03 Oct 2020 21:33:19

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:40:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-03T17:33:05', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'fac8a870-7b41-4861-9dce-8a311a095ba6'	System	03 Oct 2020 21:33:19
User entered 'None (0)'	System	03 Oct 2020 21:33:19

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:40:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-03T17:33:08', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'fac8a870-7b41-4861-9dce-8a311a095ba6'	System	03 Oct 2020 21:33:19
User entered 'None (0)'	System	03 Oct 2020 21:33:19

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:40:43

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-03T17:33:13', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'fac8a870-7b41-4861-9dce-8a311a095ba6'	System	03 Oct 2020 21:33:19
User entered 'No (N)'	System	03 Oct 2020 21:33:19

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:40:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-03T17:33:16', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'fac8a870-7b41-4861-9dce-8a311a095ba6'	System	03 Oct 2020 21:33:19
User entered '03 Oct 2020 17:33'	System	03 Oct 2020 21:33:19

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:40:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:40:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
Data entry locked.	System	28 Sep 2020 15:00:21
User entered 'Day 7'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:40:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-04T18:32:34', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '7293c26e-02da-4a60-910e-6c385fde71f6'	System	04 Oct 2020 22:32:59
User entered 'None (0)'	System	04 Oct 2020 22:32:59

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:40:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-04T18:32:36', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '7293c26e-02da-4a60-910e-6c385fde71f6'	System	04 Oct 2020 22:32:59
User entered 'None (0)'	System	04 Oct 2020 22:32:59

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:40:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-04T18:32:38', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '7293c26e-02da-4a60-910e-6c385fde71f6'	System	04 Oct 2020 22:32:59
User entered 'None (0)'	System	04 Oct 2020 22:32:59

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:40:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-04T18:32:40', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '7293c26e-02da-4a60-910e-6c385fde71f6'	System	04 Oct 2020 22:32:59
User entered 'None (0)'	System	04 Oct 2020 22:32:59

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:40:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-04T18:32:42', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '7293c26e-02da-4a60-910e-6c385fde71f6'	System	04 Oct 2020 22:32:59
User entered 'None (0)'	System	04 Oct 2020 22:32:59

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:40:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-04T18:32:44', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '7293c26e-02da-4a60-910e-6c385fde71f6'	System	04 Oct 2020 22:32:59
User entered 'None (0)'	System	04 Oct 2020 22:32:59

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:40:43

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-04T18:32:55', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '7293c26e-02da-4a60-910e-6c385fde71f6'	System	04 Oct 2020 22:32:59
User entered 'No (N)'	System	04 Oct 2020 22:32:59

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:40:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-10-04T18:32:57', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '7293c26e-02da-4a60-910e-6c385fde71f6'	System	04 Oct 2020 22:32:59
User entered '04 Oct 2020 18:32'	System	04 Oct 2020 22:32:59

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:40:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 15:00:21

US3952158

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:40:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:30:32
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 15:00:21

US3952158

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:40:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:11:56
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	07 Oct 2020 17:42:05

US3952158

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:40:43

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:11:56
User entered '05 Oct 2020'	(b) (4) Nick Bart (b) (4)	07 Oct 2020 17:42:05

US3952158

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:40:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:11:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Nick Bart (b) (4)	07 Oct 2020 17:42:05

US3952158

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:40:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:11:56
User entered empty.	(b) (4) Nick Bart (b) (4)	07 Oct 2020 17:42:05

US3952158

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:40:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:11:56
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	07 Oct 2020 17:41:58

US3952158

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:40:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:40:11
User entered 'I'	System	07 Oct 2020 17:41:58

US3952158

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:40:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:39:10
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:11:56
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	16 Oct 2020 13:44:47

US3952158

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:40:43

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:39:10
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:11:56
User entered '15 Oct 2020'	(b) (4) Nick Bart (b) (4)	16 Oct 2020 13:44:47

US3952158

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:40:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:39:10
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:11:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Nick Bart (b) (4)	16 Oct 2020 13:44:47

US3952158

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:40:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:39:10
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:11:56
User entered empty.	(b) (4) Nick Bart (b) (4)	16 Oct 2020 13:44:47

US3952158

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:40:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:39:10
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:11:56
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	16 Oct 2020 13:44:38

US3952158

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:40:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:39:10
User entered 'I'	System	16 Oct 2020 13:44:38

US3952158

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:40:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:35:08
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:11:56
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:30:25

US3952158

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:40:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:35:08
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:11:56
User closed query 'PER CDM: Re-Query: Per previous response noted. Visit 1 Day1 was on 28-SEP-20. However, Safety Call Day 22 'Date of Contact or Contact Attempt' (23-OCT-20) is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Dec 2020 05:17:36
Query 'PER CDM: Re-Query: Per previous response noted. Visit 1 Day1 was on 28-SEP-20. However, Safety Call Day 22 'Date of Contact or Contact Attempt' (23-OCT-20) is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify. Thank you. ' answered with 'Deviation filed' (Site from DM).	Nick Bart (b) (4)	23 Dec 2020 16:37:20
User opened query 'PER CDM: Re-Query: Per previous response noted. Visit 1 Day1 was on 28-SEP-20. However, Safety Call Day 22 'Date of Contact or Contact Attempt' (23-OCT-20) is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 11:44:13
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	20 Nov 2020 11:44:06
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'First attempt made on 19Oct2020, attempts were made over multiple dates, subject never completed phone call visit' (Site from System).	Nick Bart (b) (4)	27 Oct 2020 18:31:31

US3952158

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:40:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	27 Oct 2020 18:30:25
User entered '23 Oct 2020'	Nick Bart (b) (4) [REDACTED]	27 Oct 2020 18:30:25

US3952158

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:40:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:35:08
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:11:56
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:30:25

US3952158

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:40:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:35:08
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:11:56
User entered 'No response after four attempts to reach subject'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:30:25

US3952158

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:40:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:35:08
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:11:56
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:31:37

US3952158

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:40:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:35:08
User entered 'I'	System	27 Oct 2020 18:31:37

US3952158

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:40:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:31:50

US3952158

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:40:43

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered '26 Oct 2020'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:31:50

US3952158

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:40:43

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered 'Clinic (Clinic)'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:31:50

US3952158

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:40:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User entered 'VISIT2'	System	27 Oct 2020 18:31:50

US3952158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User accepted default value 'Pre-Dose (PREDOSE)'	Nick Bart (b) (4)	27 Oct 2020 18:35:27

US3952158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:35:27

US3952158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered '26 Oct 2020'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:35:27

US3952158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:43

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered '10:11'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:35:27

US3952158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User entered '26 Oct 2020 10:11'	System	27 Oct 2020 18:35:27

US3952158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:43

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered '37.0' C	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:35:27

US3952158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered 'Oral (Oral)'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:35:27

US3952158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered empty.	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:35:27

US3952158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User closed query 'Per CDM: Per CCG V2.0 page 50, Pulse ≥ 101 or ≤ 54 (beats/min) is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Dec 2020 17:41:45
Query 'Per CDM: Per CCG V2.0 page 50, Pulse ≥ 101 or ≤ 54 (beats/min) is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you.' answered with 'NCS per investigator.' (Site from DM).	Atanas Filev (b) (4) (b) (4)	17 Dec 2020 16:55:24
User entered '104' reason for change: Data Entry Error	Atanas Filev (b) (4) (b) (4)	17 Dec 2020 16:55:13
User opened query 'Per CDM: Per CCG V2.0 page 50, Pulse ≥ 101 or ≤ 54 (beats/min) is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 08:34:37
User entered '107'	Nick Bart (b) (4)	27 Oct 2020 18:35:27

US3952158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User entered 'bpm'	System	27 Oct 2020 18:35:27

US3952158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered '12'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:35:27

US3952158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User entered 'breaths/min'	System	27 Oct 2020 18:35:27

US3952158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:43

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered '139'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:35:27

US3952158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User entered 'mmHg'	System	27 Oct 2020 18:35:27

US3952158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User closed query 'Per CDM: Per CCG V2.0 page 50, DBP \geq 91 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 17:42:14
Query 'Per CDM: Per CCG V2.0 page 50, DBP \geq 91 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you.' answered with 'Considered as CS by Investigator. AE recorded at the time of measurement, will be entered into EDC. ' (Site from DM).	Atanas Filev (b) (4)	17 Dec 2020 16:55:07
User opened query 'Per CDM: Per CCG V2.0 page 50, DBP \geq 91 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 08:33:49
User entered '101'	Nick Bart (b) (4)	27 Oct 2020 18:35:27

US3952158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User entered 'mmHg'	System	27 Oct 2020 18:35:27

US3952158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User accepted default value 'Post-Dose (POSTDOSE)'	Nick Bart (b) (4)	27 Oct 2020 18:35:27

US3952158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:35:27

US3952158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered empty.	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:35:27

US3952158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:43

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered empty.	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:35:27

US3952158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User entered empty.	System	27 Oct 2020 18:35:27

US3952158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered empty.	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:35:27

US3952158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered empty.	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:35:27

US3952158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered empty.	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:35:27

US3952158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered empty.	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:35:27

US3952158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User entered empty.	System	27 Oct 2020 18:35:27

US3952158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered empty.	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:35:27

US3952158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User entered empty.	System	27 Oct 2020 18:35:27

US3952158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered empty.	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:35:27

US3952158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User entered empty.	System	27 Oct 2020 18:35:27

US3952158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered empty.	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:35:27

US3952158

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:43

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User entered empty.	System	27 Oct 2020 18:35:27

US3952158

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:40:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:32:07

US3952158

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:40:43

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered empty.	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:32:07

US3952158

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:40:43

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:34:44

US3952158

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:40:43

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:34:44

US3952158

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:40:43

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered empty.	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:34:44

US3952158

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:40:43

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User entered empty.	System	27 Oct 2020 18:34:44

US3952158

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:40:43

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered empty.	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:34:44

US3952158

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:40:43

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered empty.	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:34:44

US3952158

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:40:43

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User entered empty.	System	27 Oct 2020 18:34:44

US3952158

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:40:43

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered empty.	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:34:44

US3952158

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:40:43

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User entered empty.	System	27 Oct 2020 18:34:44

US3952158

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:40:43

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User entered empty.	System	27 Oct 2020 18:34:44

US3952158

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:40:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:32:24

US3952158

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:40:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered '26 Oct 2020'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:32:24

US3952158

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:40:43

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered '12:09'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:32:24

US3952158

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:40:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User entered '26 Oct 2020 12:09'	System	27 Oct 2020 18:32:24

US3952158

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:40:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered '26 Oct 2020'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:32:38

US3952158

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:40:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Nick Bart (b) (4)	27 Oct 2020 18:32:38

US3952158

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:40:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:32:38

US3952158

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:40:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered '12:14'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:32:38

US3952158

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:40:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User entered '26 Oct 2020 12:14'	System	27 Oct 2020 18:32:38

US3952158

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:40:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Nick Bart (b) (4)	27 Oct 2020 18:32:38

US3952158

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:40:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:32:38

US3952158

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:40:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered empty.	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:32:38

US3952158

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:40:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User entered empty.	System	27 Oct 2020 18:32:38

US3952158

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:40:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:31:57

US3952158

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:40:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User entered 'I'	System	27 Oct 2020 18:31:57

US3952158

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:40:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:46:39
User entered 'Yes (Y)'	(b) (4) chrishea Harvey (b) (4)	17 Nov 2020 13:35:48

US3952158

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:40:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:46:39
User entered '02 Nov 2020'	(b) (4) chrishea Harvey (b) (4)	17 Nov 2020 13:35:48

US3952158

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:40:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:46:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) chrishea Harvey (b) (4)	17 Nov 2020 13:35:48

US3952158

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:40:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:46:39
User entered empty.	(b) (4) chrishea Harvey (b) (4)	17 Nov 2020 13:35:48

US3952158

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:40:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:46:39
User entered 'Yes (Y)'	(b) (4) chrishea Harvey (b) (4)	17 Nov 2020 13:36:03

US3952158

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:40:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User entered 'I'	System	17 Nov 2020 13:36:03

US3952158

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:40:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:11:56
User entered 'Yes (Y)'	(b) (4) chrishea Harvey (b) (4)	17 Nov 2020 14:50:15

US3952158

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:40:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:11:56
User entered '09 Nov 2020'	(b) (4) chrishea Harvey (b) (4)	17 Nov 2020 14:50:15

US3952158

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:40:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:11:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) chrishea Harvey (b) (4)	17 Nov 2020 14:50:15

US3952158

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:40:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:11:56
User entered empty.	(b) (4) chrishea Harvey (b) (4)	17 Nov 2020 14:50:15

US3952158

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:40:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:11:56
User entered 'Yes (Y)'	(b) (4) chrishea Harvey (b) (4)	17 Nov 2020 14:50:38

US3952158

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:40:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User entered 'I'	System	17 Nov 2020 14:50:38

US3952158

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:40:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:11:56
User entered 'Yes (Y)'	(b) (4) chrishea Harvey (b) (4)	17 Nov 2020 14:51:01

US3952158

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:40:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:11:56
User entered '16 Nov 2020'	(b) (4) chrishea Harvey (b) (4)	17 Nov 2020 14:51:01

US3952158

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:40:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:11:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) chrishea Harvey (b) (4)	17 Nov 2020 14:51:01

US3952158

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:40:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:11:56
User entered empty.	(b) (4) chrishea Harvey (b) (4)	17 Nov 2020 14:51:01

US3952158

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:40:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:11:56
User entered 'Yes (Y)'	(b) (4) chrishea Harvey (b) (4)	17 Nov 2020 14:51:12

US3952158

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:40:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User entered 'I'	System	17 Nov 2020 14:51:12

US3952158

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:40:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	24 Nov 2020 15:50:33

US3952158

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:40:43

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered '23 Nov 2020'	(b) (4) Nick Bart (b) (4)	24 Nov 2020 15:50:33

US3952158

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:40:43

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered 'Clinic (Clinic)'	(b) (4) Nick Bart (b) (4)	24 Nov 2020 15:50:33

US3952158

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:40:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User entered 'VISIT3'	System	24 Nov 2020 15:50:33

US3952158

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	24 Nov 2020 15:50:51

US3952158

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered '23 Nov 2020'	(b) (4) Nick Bart (b) (4)	24 Nov 2020 15:50:51

US3952158

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered '09:05'	(b) (4) Nick Bart (b) (4)	24 Nov 2020 15:50:51

US3952158

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User entered '23 Nov 2020 09:05'	System	24 Nov 2020 15:50:51

US3952158

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered '36.9' C	(b) (4) Nick Bart (b) (4)	24 Nov 2020 15:50:51

US3952158

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered 'Oral (Oral)'	(b) (4) Nick Bart (b) (4)	24 Nov 2020 15:50:51

US3952158

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered empty.	(b) (4) Nick Bart (b) (4)	24 Nov 2020 15:50:51

US3952158

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered '97'	(b) (4) Nick Bart (b) (4)	24 Nov 2020 15:50:51

US3952158

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User entered 'bpm'	System	24 Nov 2020 15:50:51

US3952158

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered '14'	(b) (4) Nick Bart (b) (4)	24 Nov 2020 15:50:51

US3952158

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User entered 'breaths/min'	System	24 Nov 2020 15:50:51

US3952158

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered '133'	(b) (4) Nick Bart (b) (4)	24 Nov 2020 15:50:51

US3952158

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User entered 'mmHg'	System	24 Nov 2020 15:50:51

US3952158

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User closed query 'Per CDM: Per CCG V2.0 page 53, Diastolic Blood Pressure \geq 91 mmHg is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you ' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 12:34:06
Query 'Per CDM: Per CCG V2.0 page 53, Diastolic Blood Pressure \geq 91 mmHg is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you ' answered with 'NCS' (Site from DM).	Nick Bart (b) (4)	23 Dec 2020 16:39:41
User opened query 'Per CDM: Per CCG V2.0 page 53, Diastolic Blood Pressure \geq 91 mmHg is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you ' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 11:06:17
User entered '94'	Nick Bart (b) (4)	24 Nov 2020 15:50:51

US3952158

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User entered 'mmHg'	System	24 Nov 2020 15:50:51

US3952158

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 20:33:37

US3952158

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37

US3952158

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:40:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	24 Nov 2020 15:50:58

US3952158

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:40:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered empty.	(b) (4) Nick Bart (b) (4)	24 Nov 2020 15:50:58

US3952158

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:40:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	24 Nov 2020 15:51:09

US3952158

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:40:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered '23 Nov 2020'	(b) (4) Nick Bart (b) (4)	24 Nov 2020 15:51:09

US3952158

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:40:43

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered '09:35'	(b) (4) Nick Bart (b) (4)	24 Nov 2020 15:51:09

US3952158

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:40:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User entered '23 Nov 2020 09:35'	System	24 Nov 2020 15:51:09

US3952158

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:40:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:10:24
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	24 Nov 2020 15:50:20

US3952158

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:40:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User entered '1'	System	24 Nov 2020 15:50:20

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '25 Nov 2020 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '29 Nov 2020 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '02 Dec 2020 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '06 Dec 2020 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-12-09T06:47:22', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '34d99727-6de1-4103-9fc1-44cd31902a8f'	System	09 Dec 2020 11:47:38
User entered 'No (N)'	System	09 Dec 2020 11:47:38

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-12-09T06:47:27', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '34d99727-6de1-4103-9fc1-44cd31902a8f'	System	09 Dec 2020 11:47:38
User entered 'No (N)'	System	09 Dec 2020 11:47:38

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-12-09T06:47:33', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '34d99727-6de1-4103-9fc1-44cd31902a8f' User entered '09 Dec 2020 06:47:33'	System	09 Dec 2020 11:47:38
	System	09 Dec 2020 11:47:38

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '09 Dec 2020 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '13 Dec 2020 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-12-17T11:14:29', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '17e6368d-8730-444a-978f-0281279aa37c'	System	17 Dec 2020 16:14:40
User entered 'No (N)'	System	17 Dec 2020 16:14:40

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-12-17T11:14:32', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '17e6368d-8730-444a-978f-0281279aa37c'	System	17 Dec 2020 16:14:40
User entered 'No (N)'	System	17 Dec 2020 16:14:40

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-12-17T11:14:37', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '17e6368d-8730-444a-978f-0281279aa37c'	System	17 Dec 2020 16:14:40
User entered '17 Dec 2020 11:14:37'	System	17 Dec 2020 16:14:40

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '16 Dec 2020 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '20 Dec 2020 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-12-23T07:00:42', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '990634da-4098-460e-a997-14c69b2c926c'	System	23 Dec 2020 12:00:59
User entered 'No (N)'	System	23 Dec 2020 12:00:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-12-23T07:00:51', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '990634da-4098-460e-a997-14c69b2c926c'	System	23 Dec 2020 12:00:59
User entered 'No (N)'	System	23 Dec 2020 12:00:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-12-23T07:00:56', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '990634da-4098-460e-a997-14c69b2c926c'	System	23 Dec 2020 12:00:59
User entered '23 Dec 2020 07:00:56'	System	23 Dec 2020 12:00:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '23 Dec 2020 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '27 Dec 2020 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-12-30T08:24:48', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '9eae3bf8-10c5-49a9-995b-50395a1c3b56'	System	30 Dec 2020 13:25:00
User entered 'No (N)'	System	30 Dec 2020 13:25:00

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-12-30T08:24:52', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '9eae3bf8-10c5-49a9-995b-50395a1c3b56'	System	30 Dec 2020 13:25:00
User entered 'No (N)'	System	30 Dec 2020 13:25:00

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2020-12-30T08:24:56', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '9eae3bf8-10c5-49a9-995b-50395a1c3b56'	System	30 Dec 2020 13:25:00
User entered '30 Dec 2020 08:24:56'	System	30 Dec 2020 13:25:00

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '30 Dec 2020 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '03 Jan 2021 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2021-01-06T18:44:06', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'b95dabfc-06f1-436e-81f1-def7f89ee89a'	System	06 Jan 2021 23:44:18
User entered 'No (N)'	System	06 Jan 2021 23:44:18

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2021-01-06T18:44:09', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'b95dabfc-06f1-436e-81f1-def7f89ee89a'	System	06 Jan 2021 23:44:18
User entered 'No (N)'	System	06 Jan 2021 23:44:18

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2021-01-06T18:44:13', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'b95dabfc-06f1-436e-81f1-def7f89ee89a'	System	06 Jan 2021 23:44:18
User entered '06 Jan 2021 18:44:13'	System	06 Jan 2021 23:44:18

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '06 Jan 2021 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '10 Jan 2021 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2021-01-13T01:00:05', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '2adbf5f9-c848-46e7-8522-0dd70589b10b'	System	13 Jan 2021 06:00:17
User entered 'No (N)'	System	13 Jan 2021 06:00:17

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2021-01-13T01:00:08', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '2adbf5f9-c848-46e7-8522-0dd70589b10b'	System	13 Jan 2021 06:00:17
User entered 'No (N)'	System	13 Jan 2021 06:00:17

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2021-01-13T01:00:11', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '2adbf5f9-c848-46e7-8522-0dd70589b10b'	System	13 Jan 2021 06:00:17
User entered '13 Jan 2021 01:00:11'	System	13 Jan 2021 06:00:17

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '13 Jan 2021 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '17 Jan 2021 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2021-01-20T21:10:40', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '4ef3db75-595b-4015-830c-fd7e0353155a'	System	21 Jan 2021 02:10:51
User entered 'No (N)'	System	21 Jan 2021 02:10:51

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2021-01-20T21:10:43', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '4ef3db75-595b-4015-830c-fd7e0353155a'	System	21 Jan 2021 02:10:51
User entered 'No (N)'	System	21 Jan 2021 02:10:51

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2021-01-20T21:10:46', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '4ef3db75-595b-4015-830c-fd7e0353155a'	System	21 Jan 2021 02:10:51
User entered '20 Jan 2021 21:10:46'	System	21 Jan 2021 02:10:51

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '20 Jan 2021 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '24 Jan 2021 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2021-01-27T02:38:28', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'd83868d5-a1ef-4f9f-94f1-2cc2fcd821c8'	System	27 Jan 2021 07:38:39
User entered 'No (N)'	System	27 Jan 2021 07:38:39

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2021-01-27T02:38:31', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'd83868d5-a1ef-4f9f-94f1-2cc2fcd821c8'	System	27 Jan 2021 07:38:39
User entered 'No (N)'	System	27 Jan 2021 07:38:39

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2021-01-27T02:38:36', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'd83868d5-a1ef-4f9f-94f1-2cc2fcd821c8'	System	27 Jan 2021 07:38:39
User entered '27 Jan 2021 02:38:36'	System	27 Jan 2021 07:38:39

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '27 Jan 2021 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '31 Jan 2021 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2021-02-04T15:27:15', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'a0c8f8d4-0196-4963-9d26-b40cbabfe987'	System	04 Feb 2021 20:27:29
User entered 'No (N)'	System	04 Feb 2021 20:27:29

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2021-02-04T15:27:20', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'a0c8f8d4-0196-4963-9d26-b40cbabfe987'	System	04 Feb 2021 20:27:29
User entered 'No (N)'	System	04 Feb 2021 20:27:29

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2021-02-04T15:27:23', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'a0c8f8d4-0196-4963-9d26-b40cbabfe987'	System	04 Feb 2021 20:27:29
User entered '04 Feb 2021 15:27:23'	System	04 Feb 2021 20:27:29

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '03 Feb 2021 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '07 Feb 2021 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2021-02-12T14:39:57', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '28b19405-b090-40e3-934a-e82cfc79466b'	System	12 Feb 2021 19:40:06
User entered 'No (N)'	System	12 Feb 2021 19:40:06

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2021-02-12T14:40:00', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '28b19405-b090-40e3-934a-e82cfc79466b'	System	12 Feb 2021 19:40:06
User entered 'No (N)'	System	12 Feb 2021 19:40:06

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2021-02-12T14:40:03', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '28b19405-b090-40e3-934a-e82cfc79466b'	System	12 Feb 2021 19:40:06
User entered '12 Feb 2021 14:40:03'	System	12 Feb 2021 19:40:06

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '10 Feb 2021 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '14 Feb 2021 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2021-02-17T20:56:55', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '76c86a37-3b3c-4d3d-9e19-918ec93d0226'	System	18 Feb 2021 01:57:05
User entered 'No (N)'	System	18 Feb 2021 01:57:05

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2021-02-17T20:56:58', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '76c86a37-3b3c-4d3d-9e19-918ec93d0226'	System	18 Feb 2021 01:57:05
User entered 'No (N)'	System	18 Feb 2021 01:57:05

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2021-02-17T20:57:01', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '76c86a37-3b3c-4d3d-9e19-918ec93d0226'	System	18 Feb 2021 01:57:05
User entered '17 Feb 2021 20:57:01'	System	18 Feb 2021 01:57:05

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '17 Feb 2021 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '21 Feb 2021 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2021-02-24T15:04:25-05:00', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'd86c3baf-972e-49ce-8f99-b1bfe80e11fa' User entered 'No (N)'	System	24 Feb 2021 20:12:42
	System	24 Feb 2021 20:12:42

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2021-02-24T15:04:27-05:00', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'd86c3baf-972e-49ce-8f99-b1bfe80e11fa' User entered 'No (N)'	System	24 Feb 2021 20:12:42

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2021-02-24T15:04:30-05:00', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'd86c3baf-972e-49ce-8f99-b1bfe80e11fa' User entered '24 Feb 2021 15:04:30'	System	24 Feb 2021 20:12:42
	System	24 Feb 2021 20:12:42

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '24 Feb 2021 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '28 Feb 2021 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2021-03-04T18:37:18-05:00', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '1475b09b-fbe3-47f5-8424-30dc769227c4'	System	04 Mar 2021 23:37:59
User entered 'No (N)'	System	04 Mar 2021 23:37:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2021-03-04T18:37:20-05:00', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '1475b09b-fbe3-47f5-8424-30dc769227c4'	System	04 Mar 2021 23:37:59
User entered 'No (N)'	System	04 Mar 2021 23:37:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2021-03-04T18:37:24-05:00', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '1475b09b-fbe3-47f5-8424-30dc769227c4'	System	04 Mar 2021 23:37:59
User entered '04 Mar 2021 18:37:24'	System	04 Mar 2021 23:37:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '03 Mar 2021 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '07 Mar 2021 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2021-03-10T13:52:18-05:00', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '2aca6843-181a-41dd-a0ce-ea2f90c995e0'	System	10 Mar 2021 18:52:34
User entered 'No (N)'	System	10 Mar 2021 18:52:34

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2021-03-10T13:52:21-05:00', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '2aca6843-181a-41dd-a0ce-ea2f90c995e0'	System	10 Mar 2021 18:52:34
User entered 'No (N)'	System	10 Mar 2021 18:52:34

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2021-03-10T13:52:27-05:00', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '2aca6843-181a-41dd-a0ce-ea2f90c995e0' User entered '10 Mar 2021 13:52:27'	System	10 Mar 2021 18:52:34
	System	10 Mar 2021 18:52:34

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '10 Mar 2021 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '14 Mar 2021 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2021-03-17T06:26:05-04:00', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '820b4433-332f-4d4c-8543-03b380182c3a'	System	17 Mar 2021 10:26:14
User entered 'No (N)'	System	17 Mar 2021 10:26:14

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2021-03-17T06:26:08-04:00', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '820b4433-332f-4d4c-8543-03b380182c3a'	System	17 Mar 2021 10:26:14
User entered 'No (N)'	System	17 Mar 2021 10:26:14

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2021-03-17T06:26:11-04:00', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '820b4433-332f-4d4c-8543-03b380182c3a'	System	17 Mar 2021 10:26:14
User entered '17 Mar 2021 06:26:11'	System	17 Mar 2021 10:26:14

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '17 Mar 2021 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '21 Mar 2021 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2021-03-24T02:06:12-04:00', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'b393d070-9236-4aa6-81d7-e49dd2d70f36'	System	24 Mar 2021 06:06:21
User entered 'No (N)'	System	24 Mar 2021 06:06:21

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2021-03-24T02:06:14-04:00', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'b393d070-9236-4aa6-81d7-e49dd2d70f36'	System	24 Mar 2021 06:06:21
User entered 'No (N)'	System	24 Mar 2021 06:06:21

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2021-03-24T02:06:17-04:00', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'b393d070-9236-4aa6-81d7-e49dd2d70f36'	System	24 Mar 2021 06:06:21
User entered '24 Mar 2021 02:06:17'	System	24 Mar 2021 06:06:21

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '24 Mar 2021 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '28 Mar 2021 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2021-03-31T08:22:53-04:00', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '40761cca-1869-4bd3-b342-3943a70bb5c2'	System	31 Mar 2021 12:23:05
User entered 'No (N)'	System	31 Mar 2021 12:23:05

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2021-03-31T08:22:57-04:00', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '40761cca-1869-4bd3-b342-3943a70bb5c2'	System	31 Mar 2021 12:23:05
User entered 'No (N)'	System	31 Mar 2021 12:23:05

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2021-03-31T08:23:00-04:00', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '40761cca-1869-4bd3-b342-3943a70bb5c2'	System	31 Mar 2021 12:23:05
User entered '31 Mar 2021 08:23:00'	System	31 Mar 2021 12:23:05

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '31 Mar 2021 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '04 Apr 2021 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2021-04-08T10:32:12-04:00', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'd52551d9-743b-44fe-9483-c657ea92d7a9' User entered 'No (N)'	System	08 Apr 2021 14:32:25
	System	08 Apr 2021 14:32:25

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2021-04-08T10:32:14-04:00', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'd52551d9-743b-44fe-9483-c657ea92d7a9'	System	08 Apr 2021 14:32:25
User entered 'No (N)'	System	08 Apr 2021 14:32:25

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2021-04-08T10:32:18-04:00', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: 'd52551d9-743b-44fe-9483-c657ea92d7a9'	System	08 Apr 2021 14:32:25
User entered '08 Apr 2021 10:32:18'	System	08 Apr 2021 14:32:25

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '07 Apr 2021 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '11 Apr 2021 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2021-04-14T06:48:43-04:00', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '235ff116-c170-477b-8552-47074b3be1ed' User entered 'No (N)'	System	14 Apr 2021 10:48:52
	System	14 Apr 2021 10:48:52

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2021-04-14T06:48:45-04:00', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '235ff116-c170-477b-8552-47074b3be1ed'	System	14 Apr 2021 10:48:52
User entered 'No (N)'	System	14 Apr 2021 10:48:52

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2021-04-14T06:48:48-04:00', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '235ff116-c170-477b-8552-47074b3be1ed' User entered '14 Apr 2021 06:48:48'	System	14 Apr 2021 10:48:52
	System	14 Apr 2021 10:48:52

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '14 Apr 2021 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '18 Apr 2021 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2021-04-21T22:29:45-04:00', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '6b6211a5-6aa4-4966-93dc-9a7bfe7eaaf5'	System	22 Apr 2021 02:29:59
User entered 'No (N)'	System	22 Apr 2021 02:29:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2021-04-21T22:29:51-04:00', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '6b6211a5-6aa4-4966-93dc-9a7bfe7eaaf5'	System	22 Apr 2021 02:29:59
User entered 'No (N)'	System	22 Apr 2021 02:29:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2021-04-21T22:29:56-04:00', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '6b6211a5-6aa4-4966-93dc-9a7bfe7eaaf5'	System	22 Apr 2021 02:29:59
User entered '21 Apr 2021 22:29:56'	System	22 Apr 2021 02:29:59

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '21 Apr 2021 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '25 Apr 2021 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2021-04-28T13:30:48-04:00', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '25f4c611-a3f1-41a5-9715-d0fa4abac404'	System	28 Apr 2021 21:48:07
User entered 'No (N)'	System	28 Apr 2021 21:48:07

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2021-04-28T13:30:51-04:00', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '25f4c611-a3f1-41a5-9715-d0fa4abac404'	System	28 Apr 2021 21:48:07
User entered 'No (N)'	System	28 Apr 2021 21:48:07

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2021-04-28T13:31:01-04:00', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '25f4c611-a3f1-41a5-9715-d0fa4abac404'	System	28 Apr 2021 21:48:07
User entered '28 Apr 2021 13:31:01'	System	28 Apr 2021 21:48:07

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '28 Apr 2021 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '02 May 2021 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '05 May 2021 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '09 May 2021 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '12 May 2021 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '16 May 2021 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '19 May 2021 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '23 May 2021 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '26 May 2021 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '30 May 2021 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '02 Jun 2021 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '06 Jun 2021 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '09 Jun 2021 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '13 Jun 2021 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '16 Jun 2021 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '20 Jun 2021 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '23 Jun 2021 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '27 Jun 2021 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '30 Jun 2021 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '04 Jul 2021 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '07 Jul 2021 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '11 Jul 2021 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '14 Jul 2021 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '18 Jul 2021 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '21 Jul 2021 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '25 Jul 2021 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '28 Jul 2021 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '01 Aug 2021 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '04 Aug 2021 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '08 Aug 2021 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '11 Aug 2021 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '15 Aug 2021 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '18 Aug 2021 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '22 Aug 2021 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '25 Aug 2021 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '29 Aug 2021 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '01 Sep 2021 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '05 Sep 2021 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '08 Sep 2021 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '12 Sep 2021 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '15 Sep 2021 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '19 Sep 2021 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '22 Sep 2021 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '26 Sep 2021 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '29 Sep 2021 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '03 Oct 2021 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '06 Oct 2021 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '10 Oct 2021 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '13 Oct 2021 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '17 Oct 2021 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '20 Oct 2021 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '24 Oct 2021 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '27 Oct 2021 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '31 Oct 2021 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '03 Nov 2021 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '07 Nov 2021 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '10 Nov 2021 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '14 Nov 2021 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '17 Nov 2021 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '21 Nov 2021 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '24 Nov 2021 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '28 Nov 2021 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '01 Dec 2021 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '05 Dec 2021 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '08 Dec 2021 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '12 Dec 2021 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '15 Dec 2021 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '19 Dec 2021 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '22 Dec 2021 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '26 Dec 2021 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '29 Dec 2021 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '02 Jan 2022 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '05 Jan 2022 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '09 Jan 2022 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '12 Jan 2022 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '16 Jan 2022 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '19 Jan 2022 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '23 Jan 2022 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '26 Jan 2022 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '30 Jan 2022 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '02 Feb 2022 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '06 Feb 2022 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '09 Feb 2022 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '13 Feb 2022 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '16 Feb 2022 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '20 Feb 2022 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '23 Feb 2022 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '27 Feb 2022 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '02 Mar 2022 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '06 Mar 2022 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '09 Mar 2022 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '13 Mar 2022 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '16 Mar 2022 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '20 Mar 2022 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '23 Mar 2022 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '27 Mar 2022 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '30 Mar 2022 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '03 Apr 2022 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '06 Apr 2022 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '10 Apr 2022 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '13 Apr 2022 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '17 Apr 2022 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '20 Apr 2022 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '24 Apr 2022 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '27 Apr 2022 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '01 May 2022 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '04 May 2022 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '08 May 2022 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '11 May 2022 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '15 May 2022 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '18 May 2022 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '22 May 2022 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '25 May 2022 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '29 May 2022 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '01 Jun 2022 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '05 Jun 2022 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '08 Jun 2022 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '12 Jun 2022 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '15 Jun 2022 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '19 Jun 2022 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '22 Jun 2022 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '26 Jun 2022 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '29 Jun 2022 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '03 Jul 2022 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '06 Jul 2022 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '10 Jul 2022 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '13 Jul 2022 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '17 Jul 2022 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '20 Jul 2022 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '24 Jul 2022 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '27 Jul 2022 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '31 Jul 2022 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '03 Aug 2022 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '07 Aug 2022 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '10 Aug 2022 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '14 Aug 2022 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '17 Aug 2022 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '21 Aug 2022 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '24 Aug 2022 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '28 Aug 2022 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '31 Aug 2022 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '04 Sep 2022 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '07 Sep 2022 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '11 Sep 2022 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '14 Sep 2022 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '18 Sep 2022 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '21 Sep 2022 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '25 Sep 2022 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '28 Sep 2022 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '02 Oct 2022 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '05 Oct 2022 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '09 Oct 2022 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '12 Oct 2022 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '16 Oct 2022 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '19 Oct 2022 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '23 Oct 2022 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '26 Oct 2022 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '30 Oct 2022 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '02 Nov 2022 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '06 Nov 2022 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '09 Nov 2022 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '13 Nov 2022 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '16 Nov 2022 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '20 Nov 2022 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '23 Nov 2022 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '27 Nov 2022 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '30 Nov 2022 00:01'	System	20 Nov 2020 10:59:26

US3952158

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:59:26
Amendment Manager: User entered '04 Dec 2022 23:59'	System	20 Nov 2020 10:59:26

US3952158

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 12 Aug 2021 13:40:43

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2021-03-04T18:37:06-05:00', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '47c6cfe1-25fb-490a-b63d-1974da75e1c0'	System	04 Mar 2021 23:37:49
User entered 'No (N)'	System	04 Mar 2021 23:37:49

US3952158

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 12 Aug 2021 13:40:43

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:56:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (213b7fbf576380dc)', Time: '2021-03-04T18:37:10-05:00', User OID: 'PatientReportedOutcome (US3952158)', ODM File OID: '47c6cfe1-25fb-490a-b63d-1974da75e1c0'	System	04 Mar 2021 23:37:49
User entered '04 Mar 2021 18:37:10'	System	04 Mar 2021 23:37:49

US3952158

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:40:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:46:39
User entered 'Yes (Y)'	(b) (4) Atanas Filev (b) (4) (b) (4)	18 Dec 2020 15:27:38

US3952158

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:40:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:46:39
User entered '18 Dec 2020'	(b) (4) Atanas Filev (b) (4) (b) (4)	18 Dec 2020 15:27:38

US3952158

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:40:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:46:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Atanas Filev (b) (4) (b) (4)	18 Dec 2020 15:27:38

US3952158

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:40:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:46:39
User entered empty.	(b) (4) Atanas Filev (b) (4)	18 Dec 2020 15:27:38

US3952158

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:40:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:46:39
User entered 'Yes (Y)'	(b) (4) Atanas Filev (b) (4) (b) (4)	18 Dec 2020 15:27:44

US3952158

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:40:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:33:37
User entered 'I'	System	18 Dec 2020 15:27:44

US3952158

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:40:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:02:09
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
User entered 'Yes (Y)'	(b) (4) Atanas Filev (b) (4) (b) (4)	22 Jan 2021 00:10:01

US3952158

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:40:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:02:09
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
User entered '21 Jan 2021'	(b) (4) Atanas Filev (b) (4) (b) (4)	22 Jan 2021 00:10:01

US3952158

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:40:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:02:09
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Atanas Filev (b) (4) (b) (4)	22 Jan 2021 00:10:01

US3952158

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:40:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:02:09
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
User entered empty.	(b) (4) Atanas Filev (b) (4) (b) (4)	22 Jan 2021 00:10:01

US3952158

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:40:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:02:09
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
User entered 'Yes (Y)'	(b) (4) Atanas Filev (b) (4) (b) (4)	22 Jan 2021 00:10:05

US3952158

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:40:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:02:09
User entered '1'	System	22 Jan 2021 00:10:05

US3952158

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:40:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:02:09
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	02 Mar 2021 16:15:37

US3952158

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:40:43

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:02:09
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
User entered '23 Feb 2021'	(b) (4) Nick Bart (b) (4)	02 Mar 2021 16:15:37

US3952158

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:40:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:02:09
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) Nick Bart (b) (4)	02 Mar 2021 16:15:37

US3952158

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:40:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:02:09
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
User entered 'message left for subject who never returned call'	(b) (4) Nick Bart (b) (4)	02 Mar 2021 16:15:37

US3952158

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:40:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:02:09
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	02 Mar 2021 16:15:42

US3952158

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:40:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:02:09
User entered 'I'	System	02 Mar 2021 16:15:42

US3952158

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:40:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:02:09
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:23:33

US3952158

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:40:43

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:02:09
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
User entered '23 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:23:33

US3952158

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:40:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:02:09
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:23:33

US3952158

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:40:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:02:09
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:23:33

US3952158

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:40:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:02:09
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:23:39

US3952158

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:40:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:02:09
User entered '1'	System	23 Mar 2021 21:23:39

US3952158

Folder: Unscheduled 26 Oct 2020

Form: Unscheduled Visit Assessment

Generated On: 12 Aug 2021 13:40:43

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:21:26
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
User entered '26 Oct 2020'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:36:20

US3952158

Folder: Unscheduled 26 Oct 2020

Form: Unscheduled Visit Assessment

Generated On: 12 Aug 2021 13:40:43

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:21:26
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
User entered '0'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:36:20

US3952158

Folder: Unscheduled 26 Oct 2020

Form: Unscheduled Visit Assessment

Generated On: 12 Aug 2021 13:40:43

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:21:26
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
User entered 'I'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:36:20

US3952158

Folder: Unscheduled 26 Oct 2020

Form: Unscheduled Visit Assessment

Generated On: 12 Aug 2021 13:40:43

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:21:26
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
User entered '0'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:36:20

US3952158

Folder: Unscheduled 26 Oct 2020

Form: Unscheduled Visit Assessment

Generated On: 12 Aug 2021 13:40:43

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:21:26
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
User entered '0'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:36:20

US3952158

Folder: Unscheduled 26 Oct 2020

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:21:30
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:36:51

US3952158

Folder: Unscheduled 26 Oct 2020

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:21:30
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
User entered '26 Oct 2020'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:36:51

US3952158

Folder: Unscheduled 26 Oct 2020

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:21:30
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
User entered '10:28'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:36:51

US3952158

Folder: Unscheduled 26 Oct 2020

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:21:30
User entered '26 Oct 2020 10:28'	System	27 Oct 2020 18:36:51

US3952158

Folder: Unscheduled 26 Oct 2020

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:21:30
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:36:51

US3952158

Folder: Unscheduled 26 Oct 2020

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:21:30
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
User entered empty.	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:36:51

US3952158

Folder: Unscheduled 26 Oct 2020

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:21:30
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
User entered empty.	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:36:51

US3952158

Folder: Unscheduled 26 Oct 2020

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:21:30
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
User entered '103'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:36:51

US3952158

Folder: Unscheduled 26 Oct 2020

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:21:30
User entered 'bpm'	System	27 Oct 2020 18:36:51

US3952158

Folder: Unscheduled 26 Oct 2020

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:21:30
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:36:51

US3952158

Folder: Unscheduled 26 Oct 2020

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:21:30
User entered 'breaths/min'	System	27 Oct 2020 18:36:51

US3952158

Folder: Unscheduled 26 Oct 2020

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:21:30
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
User closed query 'Per CDM: Re-Query: Per previous response it was reported as "AE reported". However, AE is not reported for abnormal systolic blood pressure. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 08:17:50
Query 'Per CDM: Re-Query: Per previous response it was reported as "AE reported". However, AE is not reported for abnormal systolic blood pressure. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' answered with 'NCS' (Site from DM).	Nick Bart (b) (4)	29 Dec 2020 15:11:28
User opened query 'Per CDM: Re-Query: Per previous response it was reported as "AE reported". However, AE is not reported for abnormal systolic blood pressure. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 14:02:16
User closed query 'Per CDM: Per CCG V2.0 page 53, SBP ≤ 89 or ≥ 141 mmHg is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 13:59:54
Query 'Per CDM: Per CCG V2.0 page 53, SBP ≤ 89 or ≥ 141 mmHg is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' answered with 'AE reported' (Site from DM).	Nick Bart (b) (4)	23 Dec 2020 16:38:16
User opened query 'Per CDM: Per CCG V2.0 page 53, SBP ≤ 89 or ≥ 141 mmHg is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 08:46:24
User entered '146'	Nick Bart (b) (4)	27 Oct 2020 18:36:51

US3952158

Folder: Unscheduled 26 Oct 2020

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:21:30
User entered 'mmHg'	System	27 Oct 2020 18:36:51

US3952158

Folder: Unscheduled 26 Oct 2020

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:21:30
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
User closed query 'PER CDM: RE-QUERY: Per previous query response 'clinically significant'. However, AE is not reported for the abnormal Diastolic BP. Please review and update as appropriate. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Dec 2020 13:59:57
Query 'PER CDM: RE-QUERY: Per previous query response 'clinically significant'. However, AE is not reported for the abnormal Diastolic BP. Please review and update as appropriate. Thank you.' answered with 'AE reported for Diastolic BP' (Site from DM).	Nick Bart (b) (4)	23 Dec 2020 16:38:44
User opened query 'PER CDM: RE-QUERY: Per previous query response 'clinically significant'. However, AE is not reported for the abnormal Diastolic BP. Please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 16:12:34
User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	28 Oct 2020 16:12:29
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'CS, repeated' (Site from System).	Nick Bart (b) (4)	27 Oct 2020 18:37:01
User opened query 'Diastolic Blood Pressure reported System is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		27 Oct 2020 18:36:51
User entered '101'	Nick Bart (b) (4)	27 Oct 2020 18:36:51

US3952158

Folder: Unscheduled 26 Oct 2020

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:21:30
User entered 'mmHg'	System	27 Oct 2020 18:36:51

US3952158

Folder: Unscheduled 26 Oct 2020

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	01 May 2021 01:21:30

US3952158

Folder: Unscheduled 26 Oct 2020

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	01 May 2021 01:21:30

US3952158

Folder: Unscheduled 26 Oct 2020

Form: Unscheduled Visit Assessment

Generated On: 12 Aug 2021 13:40:43

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:21:34
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
User entered '26 Oct 2020'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:37:24

US3952158

Folder: Unscheduled 26 Oct 2020

Form: Unscheduled Visit Assessment

Generated On: 12 Aug 2021 13:40:43

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:21:34
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
User entered '0'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:37:24

US3952158

Folder: Unscheduled 26 Oct 2020

Form: Unscheduled Visit Assessment

Generated On: 12 Aug 2021 13:40:43

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:21:34
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
User entered 'I'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:37:24

US3952158

Folder: Unscheduled 26 Oct 2020

Form: Unscheduled Visit Assessment

Generated On: 12 Aug 2021 13:40:43

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:21:34
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
User entered '0'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:37:24

US3952158

Folder: Unscheduled 26 Oct 2020

Form: Unscheduled Visit Assessment

Generated On: 12 Aug 2021 13:40:43

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:21:34
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
User entered '0'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:37:24

US3952158

Folder: Unscheduled 26 Oct 2020

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:21:38
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:38:02

US3952158

Folder: Unscheduled 26 Oct 2020

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:21:38
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
User entered '26 Oct 2020'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:38:02

US3952158

Folder: Unscheduled 26 Oct 2020

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:21:38
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
User entered '11:35'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:38:02

US3952158

Folder: Unscheduled 26 Oct 2020

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:21:38
User entered '26 Oct 2020 11:35'	System	27 Oct 2020 18:38:02

US3952158

Folder: Unscheduled 26 Oct 2020

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:21:38
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:38:02

US3952158

Folder: Unscheduled 26 Oct 2020

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:21:38
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
User entered empty.	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:38:02

US3952158

Folder: Unscheduled 26 Oct 2020

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:21:38
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
User entered empty.	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:38:02

US3952158

Folder: Unscheduled 26 Oct 2020

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:21:38
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
User entered '104'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:38:02

US3952158

Folder: Unscheduled 26 Oct 2020

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:21:38
User entered 'bpm'	System	27 Oct 2020 18:38:02

US3952158

Folder: Unscheduled 26 Oct 2020

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:21:38
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:38:02

US3952158

Folder: Unscheduled 26 Oct 2020

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:21:38
User entered 'breaths/min'	System	27 Oct 2020 18:38:02

US3952158

Folder: Unscheduled 26 Oct 2020

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:21:38
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
User entered '153'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 18:38:02

US3952158

Folder: Unscheduled 26 Oct 2020

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:21:38
User entered 'mmHg'	System	27 Oct 2020 18:38:02

US3952158

Folder: Unscheduled 26 Oct 2020

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:21:38
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
User closed query 'PER CDM: RE-QUERY: Per previous query response 'clinically significant'. However, AE is not reported for the abnormal Diastolic BP. Please review and update as appropriate. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Dec 2020 14:04:16
Query 'PER CDM: RE-QUERY: Per previous query response 'clinically significant'. However, AE is not reported for the abnormal Diastolic BP. Please review and update as appropriate. Thank you.' answered with 'AE reported' (Site from DM).	Nick Bart (b) (4)	23 Dec 2020 16:38:59
User opened query 'PER CDM: RE-QUERY: Per previous query response 'clinically significant'. However, AE is not reported for the abnormal Diastolic BP. Please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 16:13:09
User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	28 Oct 2020 16:13:03
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'CS, not dosed, consistent with AE of Grade 3 DBP' (Site from System).	Nick Bart (b) (4)	27 Oct 2020 18:38:36
User opened query 'Diastolic Blood Pressure reported System is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		27 Oct 2020 18:38:02
User entered '108'	Nick Bart (b) (4)	27 Oct 2020 18:38:02

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Folder: Unscheduled 26 Oct 2020

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:21:38
User entered 'mmHg'	System	27 Oct 2020 18:38:02

US3952158

Folder: Unscheduled 26 Oct 2020

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	01 May 2021 01:21:38

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Folder: Unscheduled 26 Oct 2020

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:43

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:21:38

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 12 Aug 2021 13:40:43

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:39:32
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:12:34
User entered 'Yes (Y)'	(b) (4) Atanas Filev (b) (4) (b) (4)	17 Dec 2020 16:48:09

US3952158

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:40:43

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:15:51

US3952158

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:40:43

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:15:51
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:23:02
	(b) (4)	
User closed query 'Per DM CLR: Please review if this AE is a worsening of the MH condition of Hypertension. If yes, please update to reflect the term worsening as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 10:40:12
Query 'Per DM CLR: Please review if this AE is a worsening of the MH condition of Hypertension. If yes, please update to reflect the term worsening as appropriate. Otherwise, clarify.' answered with 'Per PI this is not considered worsening of medical history item of hypertension. ' (Site from DM).	Atanas Filev (b) (4)	10 Feb 2021 21:23:52
	(b) (4)	
User opened query 'Per DM CLR: Please review if this AE is a worsening of the MH condition of Hypertension. If yes, please update to reflect the term worsening as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	07 Feb 2021 20:08:58
User coded data point as SOC: Investigations, HLGT: Cardiac and vascular investigations (excl enzyme tests), HLT: Vascular tests NEC (incl blood pressure), PT: Blood pressure diastolic increased, LLT: Diastolic blood pressure increased - version MedDRA\23.0.	Coder Import (b) (4)	18 Dec 2020 15:32:41
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	18 Dec 2020 15:32:41
	(b) (4)	
Data point term sent to Coder	System	18 Dec 2020 15:32:22
User entered 'Elevated Diastolic Blood Pressure'	Atanas Filev (b) (4)	18 Dec 2020 15:31:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:40:43

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:15:51
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:23:02
	(b) (4)	
User entered 'No (N)'	Atanas Filev (b) (4)	18 Dec 2020 15:31:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:40:43

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:15:51
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:23:02
	(b) (4)	
User entered 'No (N)'	Atanas Filev (b) (4)	18 Dec 2020 15:31:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:40:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:15:51
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:23:02
	(b) (4)	
User entered 'No (N)'	Atanas Filev (b) (4)	18 Dec 2020 15:31:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:40:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:15:51
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:23:02
	(b) (4)	
User entered '26 Oct 2020'	Atanas Filev (b) (4)	18 Dec 2020 15:31:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:40:43

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:15:51
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:23:02
	(b) (4)	
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	18 Dec 2020 15:33:10
User entered empty; reason for change Data Entry Error	Atanas Filev (b) (4)	18 Dec 2020 15:33:10
	(b) (4)	
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	18 Dec 2020 15:31:48
User entered '10:11'	Atanas Filev (b) (4)	18 Dec 2020 15:31:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:40:43

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:15:51
User entered empty.	System	18 Dec 2020 15:33:10
User entered '26 Oct 2020 10:11'	System	18 Dec 2020 15:31:48

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:40:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:15:51
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:23:02
	(b) (4)	
User entered 'No (N)'	Atanas Filev (b) (4)	18 Dec 2020 15:31:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:40:43

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:15:51
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:23:02
	(b) (4)	
User entered '23 Nov 2020'	Atanas Filev (b) (4)	18 Dec 2020 15:31:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:40:43

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:15:51
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:23:02
	(b) (4)	
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	18 Dec 2020 15:33:10
User entered empty; reason for change Data Entry Error	Atanas Filev (b) (4)	18 Dec 2020 15:33:10
	(b) (4)	
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	18 Dec 2020 15:31:48
User entered '09:05'	Atanas Filev (b) (4)	18 Dec 2020 15:31:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:40:43

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:15:51
User entered empty.	System	18 Dec 2020 15:33:10
User entered '23 Nov 2020 09:05'	System	18 Dec 2020 15:31:48

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:40:43

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:15:51
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:23:02
	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	Atanas Filev (b) (4)	18 Dec 2020 15:31:48
	(b) (4)	

US3952158

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:40:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:15:51
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:23:02
	(b) (4)	
User entered 'No (N)'	Atanas Filev (b) (4)	18 Dec 2020 15:31:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:40:43

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:15:51
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:23:02
	(b) (4)	
User entered '0'	Atanas Filev (b) (4)	18 Dec 2020 15:31:48
	(b) (4)	

US3952158

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:40:43

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:15:51
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:23:02
	(b) (4)	
User entered '0'	Atanas Filev (b) (4)	18 Dec 2020 15:31:48
	(b) (4)	

US3952158

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:40:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:15:51
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:23:02
	(b) (4)	
User entered '0'	Atanas Filev (b) (4)	18 Dec 2020 15:31:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:40:43

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:15:51
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:23:02
	(b) (4)	
User entered empty.	Atanas Filev (b) (4)	18 Dec 2020 15:31:48
	(b) (4)	

US3952158

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:40:43

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:15:51
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:23:02
	(b) (4)	
User entered empty.	Atanas Filev (b) (4)	18 Dec 2020 15:31:48
	(b) (4)	

US3952158

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:40:43

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:15:51
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:23:02
	(b) (4)	
User entered empty.	Atanas Filev (b) (4)	18 Dec 2020 15:31:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:40:43

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:15:51
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:23:02
	(b) (4)	
User entered empty.	Atanas Filev (b) (4)	18 Dec 2020 15:31:48
	(b) (4)	

US3952158

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:40:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:15:51
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:23:02
	(b) (4)	
User entered '0'	Atanas Filev (b) (4)	18 Dec 2020 15:31:48
	(b) (4)	

US3952158

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:40:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:15:51
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:23:02
	(b) (4)	
User entered '0'	Atanas Filev (b) (4)	18 Dec 2020 15:31:48
	(b) (4)	

US3952158

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:40:43

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:15:51
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:23:02
	(b) (4)	
User entered '0'	Atanas Filev (b) (4)	18 Dec 2020 15:31:48
	(b) (4)	

US3952158

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:40:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:15:51
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:23:02
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 15:33:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Dec 2020 15:33:10
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Atanas Filev (b) (4)	18 Dec 2020 15:33:10
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 15:31:48
User entered empty.	Atanas Filev (b) (4)	18 Dec 2020 15:31:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:40:43

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:15:51
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:23:02
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 15:33:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Dec 2020 15:33:10
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Atanas Filev (b) (4)	18 Dec 2020 15:33:10
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 15:31:48
User entered empty.	Atanas Filev (b) (4)	18 Dec 2020 15:31:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:40:43

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:15:51
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:23:02
	(b) (4)	
User closed query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. However, this was not captured on the Dosing Discontinuation eCRF page. Please reconcile and update accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 14:05:09
Query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. However, this was not captured on the Dosing Discontinuation eCRF page. Please reconcile and update accordingly. Otherwise, clarify.' answered with 'updated' (Site from DM).	Nick Bart (b) (4)	02 Mar 2021 16:14:55
User opened query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. However, this was not captured on the Dosing Discontinuation eCRF page. Please reconcile and update accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	07 Feb 2021 20:09:07
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 15:33:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Dec 2020 15:33:10
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Atanas Filev (b) (4)	18 Dec 2020 15:33:10
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 15:31:48
User entered empty.	Atanas Filev (b) (4)	18 Dec 2020 15:31:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:40:43

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:15:51
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:23:02
	(b) (4)	
User entered 'I'	Atanas Filev (b) (4)	18 Dec 2020 15:31:48
	(b) (4)	

US3952158

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:40:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:15:51
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:23:02
	(b) (4)	
User entered '0'	Atanas Filev (b) (4)	18 Dec 2020 15:31:48
	(b) (4)	

US3952158

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:40:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:15:51
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:23:02
	(b) (4)	
User entered '0'	Atanas Filev (b) (4)	18 Dec 2020 15:31:48
	(b) (4)	

US3952158

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:40:43

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:15:51
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:23:02
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Atanas Filev (b) (4)	18 Dec 2020 15:31:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:40:43

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:15:51
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:23:02
	(b) (4)	
User entered empty.	Atanas Filev (b) (4)	18 Dec 2020 15:31:48
	(b) (4)	

US3952158

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:40:43

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:15:51
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:23:02
	(b) (4)	
User entered empty.	Atanas Filev (b) (4)	18 Dec 2020 15:31:48
	(b) (4)	

US3952158

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:40:43

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:15:51
User entered '0'	System	18 Dec 2020 15:31:48

US3952158

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:40:43

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:15:51
User entered '0'	System	18 Dec 2020 15:31:48

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:40:43

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	28 Apr 2021 22:15:51

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:40:43

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:23:02
User coded data point as SOC: Gastrointestinal disorders, HLGT: Dental and gingival conditions, HLT: Dental pain and sensation disorders, PT: Toothache, LLT: Tooth ache - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	18 Dec 2020 15:33:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Dec 2020 15:33:45
Data point term sent to Coder	System	18 Dec 2020 15:33:23
User entered 'Tooth Ache'	Atanas Filev (b) (4) (b) (4)	18 Dec 2020 15:32:29

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:40:43

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:23:02
	(b) (4)	
User entered 'No (N)'	Atanas Filev (b) (4)	18 Dec 2020 15:32:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:40:43

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:23:02
	(b) (4)	
User entered 'No (N)'	Atanas Filev (b) (4)	18 Dec 2020 15:32:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:40:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:23:02
User entered 'No (N)'	(b) (4)	
	Atanas Filev (b) (4)	18 Dec 2020 15:32:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:40:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:23:02
	(b) (4)	
User entered '14 Dec 2020'	Atanas Filev (b) (4)	18 Dec 2020 15:32:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:40:43

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:23:02
	(b) (4)	
User entered empty.	Atanas Filev (b) (4)	18 Dec 2020 15:32:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:40:43

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Dec 2020 15:32:29

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:40:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:23:02
	(b) (4)	
User entered 'Yes (Y)'	Atanas Filev (b) (4)	18 Dec 2020 15:32:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:40:43

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:23:02
	(b) (4)	
User entered empty.	Atanas Filev (b) (4)	18 Dec 2020 15:32:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:40:43

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:23:02
	(b) (4)	
User entered empty.	Atanas Filev (b) (4)	18 Dec 2020 15:32:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:40:43

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Dec 2020 15:32:29

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:40:43

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:23:02
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Atanas Filev (b) (4) (b) (4)	18 Dec 2020 15:32:29

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:40:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:23:02
	(b) (4)	
User entered 'No (N)'	Atanas Filev (b) (4)	18 Dec 2020 15:32:29
	(b) (4)	

US3952158

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:40:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:23:02
	(b) (4)	
User entered '0'	Atanas Filev (b) (4)	18 Dec 2020 15:32:29
	(b) (4)	

US3952158

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:40:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:23:02
	(b) (4)	
User entered '0'	Atanas Filev (b) (4)	18 Dec 2020 15:32:29
	(b) (4)	

US3952158

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:40:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:23:02
	(b) (4)	
User entered '0'	Atanas Filev (b) (4)	18 Dec 2020 15:32:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:40:43

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:23:02
	(b) (4)	
User entered empty.	Atanas Filev (b) (4)	18 Dec 2020 15:32:29
	(b) (4)	

US3952158

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:40:43

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:23:02
	(b) (4)	
User entered empty.	Atanas Filev (b) (4)	18 Dec 2020 15:32:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:40:43

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:23:02
	(b) (4)	
User entered empty.	Atanas Filev (b) (4)	18 Dec 2020 15:32:29
	(b) (4)	

US3952158

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:40:43

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:23:02
	(b) (4)	
User entered empty.	Atanas Filev (b) (4)	18 Dec 2020 15:32:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:40:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:23:02
	(b) (4)	
User entered '0'	Atanas Filev (b) (4)	18 Dec 2020 15:32:29
	(b) (4)	

US3952158

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:40:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:23:02
	(b) (4)	
User entered '0'	Atanas Filev (b) (4)	18 Dec 2020 15:32:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:40:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:23:02
	(b) (4)	
User entered '0'	Atanas Filev (b) (4)	18 Dec 2020 15:32:29
	(b) (4)	

US3952158

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:40:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:23:02
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 15:32:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Dec 2020 15:32:44
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Atanas Filev (b) (4)	18 Dec 2020 15:32:44
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 15:32:29
User entered empty.	Atanas Filev (b) (4)	18 Dec 2020 15:32:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:40:43

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:23:02
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 15:32:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Dec 2020 15:32:44
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Atanas Filev (b) (4)	18 Dec 2020 15:32:44
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 15:32:29
User entered empty.	Atanas Filev (b) (4)	18 Dec 2020 15:32:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:40:43

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:23:02
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 15:32:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Dec 2020 15:32:44
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Atanas Filev (b) (4)	18 Dec 2020 15:32:44
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 15:32:29
User entered empty.	Atanas Filev (b) (4)	18 Dec 2020 15:32:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:40:43

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:23:02
	(b) (4)	
User entered '0'	Atanas Filev (b) (4)	18 Dec 2020 15:32:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:40:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:23:02
	(b) (4)	
User entered '1'	Atanas Filev (b) (4)	18 Dec 2020 15:32:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:40:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:23:02
	(b) (4)	
User entered '0'	Atanas Filev (b) (4)	18 Dec 2020 15:32:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:40:43

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:23:02
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) Atanas Filev (b) (4) (b) (4)	18 Dec 2020 15:32:29

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:40:43

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:23:02
	(b) (4)	
User entered empty.	Atanas Filev (b) (4)	18 Dec 2020 15:32:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:40:43

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:23:02
	(b) (4)	
User entered empty.	Atanas Filev (b) (4)	18 Dec 2020 15:32:29
	(b) (4)	

US3952158

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:40:43

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	18 Dec 2020 15:32:29

US3952158

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:40:43

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	18 Dec 2020 15:32:29

US3952158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 12 Aug 2021 13:40:43

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:39:32
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
User entered 'Yes (Y)'	(b) (4) Atanas Filev (b) (4) (b) (4)	18 Dec 2020 15:33:33

US3952158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:40:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	18 Dec 2020 15:48:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 15:48:48
Data point term sent to Coder	System	18 Dec 2020 15:37:25
User entered 'Advil'	Atanas Filev (b) (4) (b) (4)	18 Dec 2020 15:37:08

US3952158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:40:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
User entered 'No (N)'	(b) (4)	
	Atanas Filev (b) (4)	18 Dec 2020 15:37:08
	(b) (4)	

US3952158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:40:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
User entered 'Tooth Ache'	(b) (4)	
	Atanas Filev (b) (4)	18 Dec 2020 15:37:08
	(b) (4)	

US3952158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:40:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
User entered '400'	(b) (4)	
	Atanas Filev (b) (4)	18 Dec 2020 15:37:08
	(b) (4)	

US3952158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:40:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
	(b) (4)	
User entered 'mg (mg)'	Atanas Filev (b) (4)	18 Dec 2020 15:37:08
	(b) (4)	

US3952158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:40:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
	(b) (4)	
User entered empty.	Atanas Filev (b) (4)	18 Dec 2020 15:37:08
	(b) (4)	

US3952158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:40:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
User entered 'as needed (PRN)'	(b) (4) Atanas Filev (b) (4) (b) (4)	18 Dec 2020 15:37:08

US3952158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:40:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
	(b) (4)	
User entered empty.	Atanas Filev (b) (4)	18 Dec 2020 15:37:08
	(b) (4)	

US3952158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:40:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
	(b) (4)	
User entered 'Oral (ORAL)'	Atanas Filev (b) (4)	18 Dec 2020 15:37:08
	(b) (4)	

US3952158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:40:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
	(b) (4)	
User entered empty.	Atanas Filev (b) (4)	18 Dec 2020 15:37:08
	(b) (4)	

US3952158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:40:43

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
User entered '14 Dec 2020'	(b) (4)	
	Atanas Filev (b) (4)	18 Dec 2020 15:37:08
	(b) (4)	

US3952158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:40:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
User entered '0'	(b) (4)	
	Atanas Filev (b) (4)	18 Dec 2020 15:37:08
	(b) (4)	

US3952158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:40:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
User entered 'Yes (Y)'	(b) (4) Atanas Filev (b) (4) (b) (4)	18 Dec 2020 15:37:08

US3952158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:40:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
	(b) (4)	
User entered empty.	Atanas Filev (b) (4)	18 Dec 2020 15:37:08
	(b) (4)	

US3952158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:40:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
User entered 'No (N)'	(b) (4)	
	Atanas Filev (b) (4)	18 Dec 2020 15:37:08
	(b) (4)	

US3952158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:40:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Dec 2020 15:37:08

US3952158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:40:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Dec 2020 15:37:08

US3952158

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:40:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Dec 2020 15:37:08

US3952158

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 12 Aug 2021 13:40:43

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
	(b) (4)	
User entered 'No (N)'	Nick Bart (b) (4)	11 Mar 2021 17:04:16

US3952158

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:40:43

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:53:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
	(b) (4)	
User entered '26 Oct 2020'	Atanas Filev (b) (4)	10 Feb 2021 17:08:55
	(b) (4)	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:40:43

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:53:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
	(b) (4)	
User entered 'AE (specify) (ADVERSE EVENT)'	Atanas Filev (b) (4)	10 Feb 2021 17:08:55
	(b) (4)	

US3952158

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:40:43

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:53:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:24:22
User closed query 'Per CDM review: If reason for dosing discontinuation is AE/SAE, then please consider updating the AE specify field to include the AE logline number and the '#' symbol (i.e. #6 for row 6). ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 13:41:36
Query 'Per CDM review: If reason for dosing discontinuation is AE/SAE, then please consider updating the AE specify field to include the AE logline number and the '#' symbol (i.e. #6 for row 6). ' answered with 'Updated.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 18:57:22
User entered '#1' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 18:57:08
User opened query 'Per CDM review: If reason for dosing discontinuation is AE/SAE, then please consider updating the AE specify field to include the AE logline number and the '#' symbol (i.e. #6 for row 6). ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 13:28:39
User closed query 'Per CDM: Re-Query: Per CCG V5.0 Page 57, If the Primary reason for dosing discontinuation is recorded as AE (Specify), "record the exact Adverse Event Logline #/SAE Logline # in the Other, specify field. Do not record the Adverse Event term or include any other text". Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 13:18:54
Query 'Per CDM: Re-Query: Per CCG V5.0 Page 57, If the Primary reason for dosing discontinuation is recorded as AE (Specify), "record the exact Adverse Event Logline #/SAE Logline # in the Other, specify field. Do not record the Adverse Event term or include any other text". Please review and update as appropriate. Thank you. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 19:54:03
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 19:53:57

US3952158

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:40:43

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
User opened query 'Per CDM: Re-Query: Per CCG V5.0 Page 57, If the Primary reason for dosing discontinuation is recorded as AE (Specify), "record the exact Adverse Event Logline #/SAE Logline # in the Other, specify field. Do not record the Adverse Event term or include any other text". Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 15:11:21
User closed query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #1). Thank you. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 15:11:21
Query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #1). Thank you. ' answered with 'update' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 19:50:17
User entered 'GRADE Three DIASTOLIC BLOOD PRESSURE' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Mar 2021 19:50:12
User opened query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #1). Thank you. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 14:29:10
User entered 'Grade 3 Diastolic Blood Pressure'	Atanas Filev (b) (4) (b) (4)	10 Feb 2021 17:08:55