

US3342253 (Prod: Tekton Research- Austin)

Generated By: KC Joubran

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All time stamps listed in this document are displayed in GMT

US3342253

Form: Participant Creation

Data signed: (b) (4) 29 Mar 2021 15:31:31

Generated On: 11 Aug 2021 22:35:20

Participant ID

US3342253

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

US3342253

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 29 Mar 2021 15:31:52

Generated On: 11 Aug 2021 22:35:20

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 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) 29 Mar 2021 15:31:52

Generated On: 11 Aug 2021 22:35:20

Date of Birth (MMM yyyy)	(b) (6) 1996
Age	24
Age Units	YEARS
Age (Derived)	24
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 29 Mar 2021 15:31:52

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Date of Informed Consent (<i>dd MMM yyyy</i>)	11 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) 29 Mar 2021 15:31:52

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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) 29 Mar 2021 15:31:52

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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) 29 Mar 2021 15:31:52

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Condition	PLEURISY
Start date (dd MMM yyyy)	UN OCT 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	OCT 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 29 Mar 2021 15:31:52

Generated On: 11 Aug 2021 22:35:20

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 SEP 2020
Time of assessment (00:00-23:59)	15:54 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 15:54
Height (xxx.x)	180.0 cm
Weight (xxx.x)	85.8 kg
BMI (xxx.x)	26.48148 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	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) 29 Mar 2021 15:31:52

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 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) 29 Mar 2021 15:31:52

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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

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) 29 Mar 2021 15:31:52

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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)	True
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 23:55:06

Generated On: 11 Aug 2021 22:35:20

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 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) 12 Feb 2021 23:55:06

Generated On: 11 Aug 2021 22:35:20

What was the date of randomization? (dd MMM yyyy) 11 SEP 2020

What was the participant's randomization number? 146309

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) 12 Feb 2021 23:55:06

Generated On: 11 Aug 2021 22:35:20

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) 12 Feb 2021 23:55:06

Generated On: 11 Aug 2021 22:35:20

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)	11 SEP 2020
Time of assessment (00:00-23:59)	15:54 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 15:54
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 23:55:06

Generated On: 11 Aug 2021 22:35:20

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)	11 SEP 2020
Time of assessment (00:00-23:59)	17:26 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 17:26
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 23:55:06

Generated On: 11 Aug 2021 22:35:20

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) 12 Feb 2021 23:55:06

Generated On: 11 Aug 2021 22:35:20

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) 11 SEP 2020

What was the treatment time? (00:00-23:59) 16:55 (24 HR)

Treatment Date and Time (derived) 11 SEP 2020 16:55

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) 12 Feb 2021 23:55:06

Generated On: 11 Aug 2021 22:35:20

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

11 SEP 2020

Collection time (00:00-23:59)

16:45 (24 HR)

Collection date and time (derived)

11 SEP 2020 16:45

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 23:55:06

Generated On: 11 Aug 2021 22:35:20

Collection date (dd MMM yyyy)			11 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:46	11 SEP 2020 16:46
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:55:06

Generated On: 11 Aug 2021 22:35:20

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: 11 Aug 2021 22:35:20

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 17:31

PC Open Date & Time

11 SEP 2020 17:15

PC Close Date & Time

11 SEP 2020 19:45

US3342253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.1 °F

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

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

PC Time Stamp	11 SEP 2020 21:12
PC Open Date & Time	11 SEP 2020 20:40
PC Close Date & Time	12 SEP 2020 11:59

US3342253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 17:40

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3342253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.5 °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

13 SEP 2020 17:26

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3342253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °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

14 SEP 2020 19:12

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3342253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 19:26

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3342253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 18:44

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3342253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:35:20

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

96.3 °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

17 SEP 2020 18:12

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 17:32

PC Open Date & Time

11 SEP 2020 17:15

PC Close Date & Time

11 SEP 2020 19:45

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:35:20

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

11 SEP 2020 21:13

PC Open Date & Time

11 SEP 2020 20:40

PC Close Date & Time

12 SEP 2020 11:59

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:35:20

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

12 SEP 2020 17:40

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:35:20

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

13 SEP 2020 17:26

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:35:20

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

14 SEP 2020 19:12

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:35:20

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

15 SEP 2020 19:26

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:35:20

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

16 SEP 2020 18:45

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:35:20

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

17 SEP 2020 18:11

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:20

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 ☐

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:20

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 17:33
PC Open Date & Time	11 SEP 2020 17:15
PC Close Date & Time	11 SEP 2020 19:45

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:20

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 ☐

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:20

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 21:13
PC Open Date & Time	11 SEP 2020 20:40
PC Close Date & Time	12 SEP 2020 11:59

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:20

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 ☒

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:20

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 17:41
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:20

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 ☒

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EAB) (1725)

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US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:20

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 17:26
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:20

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)

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:20

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 19:12
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:20

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 1553

EAB) (1725)

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:20

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 19:27
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:20

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

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EAB) (1725)

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:20

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 18:44
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:20

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 ☒

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:20

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 18:12
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3342253

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:55:06

Generated On: 11 Aug 2021 22:35:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342253

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:55:06

Generated On: 11 Aug 2021 22:35:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342253

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:55:06

Generated On: 11 Aug 2021 22:35:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342253

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:55:06

Generated On: 11 Aug 2021 22:35:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342253

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:55:06

Generated On: 11 Aug 2021 22:35:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342253

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:55:06

Generated On: 11 Aug 2021 22:35:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342253

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 23:55:06

Generated On: 11 Aug 2021 22:35:20

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 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

US3342253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 23:55:06

Generated On: 11 Aug 2021 22:35:20

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)	13 OCT 2020
Time of assessment (00:00-23:59)	09:25 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 09:25
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3342253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 23:55:06

Generated On: 11 Aug 2021 22:35:20

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>
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="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
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	

US3342253

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 23:55:06

Generated On: 11 Aug 2021 22:35:20

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 OCT 2020

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

US3342253

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 23:55:06

Generated On: 11 Aug 2021 22:35:20

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?

US3342253

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 23:55:06

Generated On: 11 Aug 2021 22:35:20

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

13 OCT 2020

Collection time (00:00-23:59)

10:09 (24 HR)

Collection date and time (derived)

13 OCT 2020 10:09

US3342253

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 23:55:06

Generated On: 11 Aug 2021 22:35:20

Collection date (dd MMM yyyy)			13 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:11	13 OCT 2020 10:11
Nasopharyngeal Swab 2	No		

US3342253

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:55:06

Generated On: 11 Aug 2021 22:35:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342253

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:55:06

Generated On: 11 Aug 2021 22:35:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342253

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:55:06

Generated On: 11 Aug 2021 22:35:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342253

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:55:06

Generated On: 11 Aug 2021 22:35:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342253

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:55:06

Generated On: 11 Aug 2021 22:35:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342253

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:55:06

Generated On: 11 Aug 2021 22:35:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342253

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:55:06

Generated On: 11 Aug 2021 22:35:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342253

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 23:55:06

Generated On: 11 Aug 2021 22:35:20

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 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

US3342253

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 23:55:06

Generated On: 11 Aug 2021 22:35:20

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 NOV 2020
Time of assessment (00:00-23:59)	13:41 (24 HR)
Vital Signs Date and Time (derived)	12 NOV 2020 13:41
Temperature (xxx.x)	98 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	109 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3342253

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 23:55:06

Generated On: 11 Aug 2021 22:35:20

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.

US3342253

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 23:55:06

Generated On: 11 Aug 2021 22:35:20

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 NOV 2020

Collection time (00:00-23:59)

14:19 (24 HR)

Collection date and time (derived)

12 NOV 2020 14:19

US3342253

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:55:06

Generated On: 11 Aug 2021 22:35:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342253

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	11 NOV 2020 04:12:32
Patient Cloud Open Date & Time	11 NOV 2020 00:01
Patient Cloud Close Date & Time	15 NOV 2020 23:59

US3342253

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3342253

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

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

Date and time of submission

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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	22 NOV 2020 15:58:50
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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 <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	29 NOV 2020 07:08:14
Patient Cloud Open Date & Time	29 NOV 2020 00:01
Patient Cloud Close Date & Time	03 DEC 2020 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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	06 DEC 2020 07:32:22
Patient Cloud Open Date & Time	06 DEC 2020 00:01
Patient Cloud Close Date & Time	10 DEC 2020 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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	14 DEC 2020 06:49:06
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

21 DEC 2020 07:30:22

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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	27 DEC 2020 15:25:48
Patient Cloud Open Date & Time	27 DEC 2020 00:01
Patient Cloud Close Date & Time	31 DEC 2020 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

04 JAN 2021 05:46:20

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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	13 JAN 2021 10:50:21
Patient Cloud Open Date & Time	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 JAN 2021 12:27:16

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

24 JAN 2021 09:57:12

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 FEB 2021 08:08:38

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

08 FEB 2021 07:07:28

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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 <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	14 FEB 2021 06:57:26
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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	21 FEB 2021 12:53:52
Patient Cloud Open Date & Time	21 FEB 2021 00:01
Patient Cloud Close Date & Time	25 FEB 2021 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

28 FEB 2021 15:22:50

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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 <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	07 MAR 2021 13:08:03
Patient Cloud Open Date & Time	07 MAR 2021 00:01
Patient Cloud Close Date & Time	11 MAR 2021 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

14 MAR 2021 12:51:35

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

21 MAR 2021 19:35:29

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

28 MAR 2021 07:40:27

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

04 APR 2021 10:31:07

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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 <input type="radio"/> Yes <input checked="" 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"/>
Have 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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	11 APR 2021 19:55:06
Patient Cloud Open Date & Time	11 APR 2021 00:01
Patient Cloud Close Date & Time	15 APR 2021 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

Date and time of submission

20 APR 2021 12:00:31

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

Date and time of submission

26 APR 2021 10:48:47

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

Date and time of submission

02 MAY 2021 20:44:20

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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 ☐

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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"/>

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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 ☐

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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 <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"/>

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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 <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"/>

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2021 00:01
Patient Cloud Close Date & Time	10 JUN 2021 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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 <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known 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="checkbox"/> Yes <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="checkbox"/>
Have 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="checkbox"/> Yes <input type="checkbox"/>
Please identify below 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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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 <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"/>

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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"/>

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2021 00:01
Patient Cloud Close Date & Time	08 JUL 2021 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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 <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"/>

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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 <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known 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="checkbox"/> Yes <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="checkbox"/>
Have 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="checkbox"/> Yes <input type="checkbox"/>
Please identify below 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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

Please contact your study clinic immediately. Click below to confirm that you have read this 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	18 JUL 2021 00:01
Patient Cloud Close Date & Time	22 JUL 2021 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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 <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"/>

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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 <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known 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="checkbox"/> Yes <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="checkbox"/>
Have 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="checkbox"/> Yes <input type="checkbox"/>
Please identify below 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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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"/>

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2021 00:01
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Patient Cloud Close Date & Time	19 AUG 2021 23:59
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US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known 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="checkbox"/> Yes <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="checkbox"/>
Have 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="checkbox"/> Yes <input type="checkbox"/>
Please identify below 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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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 <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known 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="checkbox"/> Yes <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="checkbox"/>
Have 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="checkbox"/> Yes <input type="checkbox"/>
Please identify below 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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2021 00:01
Patient Cloud Close Date & Time	02 SEP 2021 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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 <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"/>

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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°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 ☐

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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 <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"/>

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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 <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"/>

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01
Patient Cloud Close Date & Time	30 SEP 2021 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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 <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"/>

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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 ☐

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01
Patient Cloud Close Date & Time	14 OCT 2021 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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 <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known 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="checkbox"/> Yes <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="checkbox"/>
Have 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="checkbox"/> Yes <input type="checkbox"/>
Please identify below 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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01
Patient Cloud Close Date & Time	21 OCT 2021 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

DAY 411

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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 <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"/>

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known 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="checkbox"/> Yes <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="checkbox"/>
Have 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="checkbox"/> Yes <input type="checkbox"/>
Please identify below 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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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 <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"/>

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2021 00:01
Patient Cloud Close Date & Time	18 NOV 2021 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

DAY 439

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2021 00:01
Patient Cloud Close Date & Time	25 NOV 2021 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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 ☐

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known 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="checkbox"/> Yes <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="checkbox"/>
Have 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="checkbox"/> Yes <input type="checkbox"/>
Please identify below 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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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 <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"/>

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01
Patient Cloud Close Date & Time	16 DEC 2021 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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 <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known 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="checkbox"/> Yes <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="checkbox"/>
Have 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="checkbox"/> Yes <input type="checkbox"/>
Please identify below 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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01
Patient Cloud Close Date & Time	23 DEC 2021 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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 <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known 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="checkbox"/> Yes <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="checkbox"/>
Have 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="checkbox"/> Yes <input type="checkbox"/>
Please identify below 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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

30 DEC 2021 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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"/>

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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 <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known 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="checkbox"/> Yes <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="checkbox"/>
Have 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="checkbox"/> Yes <input type="checkbox"/>
Please identify below 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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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 <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"/>

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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 <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"/>

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 00:01
Patient Cloud Close Date & Time	03 FEB 2022 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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"/>

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2022 00:01
Patient Cloud Close Date & Time	10 FEB 2022 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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 <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known 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="checkbox"/> Yes <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="checkbox"/>
Have 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="checkbox"/> Yes <input type="checkbox"/>
Please identify below 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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2022 00:01
Patient Cloud Close Date & Time	17 FEB 2022 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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 <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"/>

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2022 00:01
Patient Cloud Close Date & Time	24 FEB 2022 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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°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 ☐

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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°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 ☐

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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 ☐

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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 ☐

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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 ☐

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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 ☐

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

[Patient Cloud Close Date & Time](#)

14 APR 2022 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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 <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"/>

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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 ☐

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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 <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"/>

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known 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="checkbox"/> Yes <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="checkbox"/>
Have 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="checkbox"/> Yes <input type="checkbox"/>
Please identify below 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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known 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="checkbox"/> Yes <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="checkbox"/>
Have 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="checkbox"/> Yes <input type="checkbox"/>
Please identify below 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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2022 00:01
Patient Cloud Close Date & Time	19 MAY 2022 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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 <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"/>

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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 <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known 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="checkbox"/> Yes <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="checkbox"/>
Have 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="checkbox"/> Yes <input type="checkbox"/>
Please identify below 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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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 <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known 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="checkbox"/> Yes <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="checkbox"/>
Have 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="checkbox"/> Yes <input type="checkbox"/>
Please identify below 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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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 <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"/>

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 00:01
Patient Cloud Close Date & Time	16 JUN 2022 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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 <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"/>

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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 <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"/>

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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 ☐

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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°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 ☐

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

[Patient Cloud Close Date & Time](#)

14 JUL 2022 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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°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 ☐

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2022 00:01
Patient Cloud Close Date & Time	21 JUL 2022 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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 <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"/>

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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"/>

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

DAY 698

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

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

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

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

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

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

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

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

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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 ☐

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

DAY 712

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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"/>

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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"/>

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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 <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"/>

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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"/>

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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 <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"/>

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2022 00:01
Patient Cloud Close Date & Time	29 SEP 2022 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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 <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"/>

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2022 00:01
Patient Cloud Close Date & Time	06 OCT 2022 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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"/>

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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 <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known 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="checkbox"/> Yes <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="checkbox"/>
Have 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="checkbox"/> Yes <input type="checkbox"/>
Please identify below 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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2022 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

DAY 775

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

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

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

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

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

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

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

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

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

[Patient Cloud Close Date & Time](#)

27 OCT 2022 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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 <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known 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="checkbox"/> Yes <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="checkbox"/>
Have 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="checkbox"/> Yes <input type="checkbox"/>
Please identify below 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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2022 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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 <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known 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="checkbox"/> Yes <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="checkbox"/>
Have 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="checkbox"/> Yes <input type="checkbox"/>
Please identify below 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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

[Patient Cloud Close Date & Time](#)

10 NOV 2022 23:59

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known 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="checkbox"/> Yes <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="checkbox"/>
Have 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="checkbox"/> Yes <input type="checkbox"/>
Please identify below 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="checkbox"/>
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="checkbox"/> Yes <input type="checkbox"/>

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

13 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2022 23:59

US3342253

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:35:20

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		28 FEB 2021 15:23:06

US3342253

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 15:31:31

Generated On: 11 Aug 2021 22:35:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342253

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 15:31:31

Generated On: 11 Aug 2021 22:35:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342253

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 15:31:31

Generated On: 11 Aug 2021 22:35:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342253

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 15:31:31

Generated On: 11 Aug 2021 22:35:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342253

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 15:31:31

Generated On: 11 Aug 2021 22:35:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342253

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 15:31:31

Generated On: 11 Aug 2021 22:35:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342253

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 15:31:31

Generated On: 11 Aug 2021 22:35:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342253

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 15:31:31

Generated On: 11 Aug 2021 22:35:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342253

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 12 Apr 2021 15:54:02

Generated On: 11 Aug 2021 22:35:20

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	05 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3342253

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Apr 2021 15:54:02

Generated On: 11 Aug 2021 22:35:20

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	05 APR 2021
Time of assessment (00:00-23:59)	09:31 (24 HR)
Vital Signs Date and Time (derived)	05 APR 2021 09:31
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3342253

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Apr 2021 15:53:58

Generated On: 11 Aug 2021 22:35:20

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.

US3342253

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Apr 2021 15:53:58

Generated On: 11 Aug 2021 22:35:20

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	05 APR 2021
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Collection time (00:00-23:59)	09:39 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	05 APR 2021 09:39
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US3342253

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 15:53:58

Generated On: 11 Aug 2021 22:35:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342253

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:20

Was Contact Attempted? Yes ☐
No ☐

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

Please select one status for the follow-up contact Contact Made ☐
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342253

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:20

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3342253

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:35:20

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"/>

US3342253

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:35:20

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 29 Mar 2021 15:31:31

Generated On: 11 Aug 2021 22:35:20

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	09 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 29 Mar 2021 15:31:31

Generated On: 11 Aug 2021 22:35:20

Date of updated informed consent (<i>dd MMM yyyy</i>)	09 MAR 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	09 MAR 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Data signed: (b) (4) 29 Mar 2021 15:31:31

Generated On: 11 Aug 2021 22:35:20

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 29 Mar 2021 15:31:31

Generated On: 11 Aug 2021 22:35:20

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
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)	09 MAR 2021
Time of assessment (00:00-23:59)	09:35 (24 HR)
Vital Signs Date and Time (derived)	09 MAR 2021 09:35
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	49 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 29 Mar 2021 15:31:31

Generated On: 11 Aug 2021 22:35:20

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
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)	09 MAR 2021
Time of assessment (00:00-23:59)	10:35 (24 HR)
Vital Signs Date and Time (derived)	09 MAR 2021 10:35
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	55 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Mar 2021 15:31:31

Generated On: 11 Aug 2021 22:35:20

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.

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Data signed: (b) (4) 29 Mar 2021 15:31:31

Generated On: 11 Aug 2021 22:35:20

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 09 MAR 2021

What was the treatment time? (00:00-23:59) 10:05 (24 HR)

Treatment Date and Time (derived) 09 MAR 2021 10:05

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

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Mar 2021 15:31:31

Generated On: 11 Aug 2021 22:35:20

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

09 MAR 2021

Collection time (00:00-23:59)

09:49 (24 HR)

Collection date and time (derived)

09 MAR 2021 09:49

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 29 Mar 2021 15:31:31

Generated On: 11 Aug 2021 22:35:20

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	09 MAR 2021
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Collection time (00:00 - 23:59)	09:51
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Collection Date and Time (derived)	09 MAR 2021 09:51
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US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 15:31:31

Generated On: 11 Aug 2021 22:35:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342253

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 15:31:52

Generated On: 11 Aug 2021 22:35:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342253

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 15:31:52

Generated On: 11 Aug 2021 22:35:20

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3342253

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Apr 2021 15:53:58

Generated On: 11 Aug 2021 22:35:20

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	05 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3342253

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Apr 2021 15:53:58

Generated On: 11 Aug 2021 22:35:20

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)	05 APR 2021
Time of assessment (00:00-23:59)	09:31 (24 HR)
Vital Signs Date and Time (derived)	05 APR 2021 09:31
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3342253

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Apr 2021 15:53:58

Generated On: 11 Aug 2021 22:35:20

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)	05 APR 2021
Time of assessment (00:00-23:59)	10:36 (24 HR)
Vital Signs Date and Time (derived)	05 APR 2021 10:36
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	51 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3342253

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Apr 2021 15:53:58

Generated On: 11 Aug 2021 22:35:20

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.

US3342253

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 12 Apr 2021 15:53:57

Generated On: 11 Aug 2021 22:35:20

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 05 APR 2021

What was the treatment time? (00:00-23:59) 10:06 (24 HR)

Treatment Date and Time (derived) 05 APR 2021 10:06

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

US3342253

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 15:53:57

Generated On: 11 Aug 2021 22:35:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342253

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 16:39:17

Generated On: 11 Aug 2021 22:35:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342253

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 16:39:17

Generated On: 11 Aug 2021 22:35:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342253

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:20

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 _____

US3342253

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:20

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)	

US3342253

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:20

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.

US3342253

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:20

Was the sample collected?

Yes ☐

No ☐

Collection date (*dd MMM yyyy*)

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

Collection date and time (derived)

US3342253

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Mar 2021 23:41:01

Generated On: 11 Aug 2021 22:35:20

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3342253

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Mar 2021 13:29:56

Generated On: 11 Aug 2021 22:35:20

AEID	
Adverse event	IDIOPATHIC PLEURISY WITH RECURRENCE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input 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)	18 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	19 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" 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"/>

US3342253

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Mar 2021 13:29:56

Generated On: 11 Aug 2021 22:35:20

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 type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input checked="" 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	False
Concomitant Medication	True
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)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 22 Mar 2021 13:34:39

Generated On: 11 Aug 2021 22:35:20

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

Yes ☒

No ☐

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

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Mar 2021 13:34:38

Generated On: 11 Aug 2021 22:35:20

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication AE IDIOPATHIC PLEURISY
WITH RECURRENCE

Dose per administration 800

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 ☐

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EAB) (1725)

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Mar 2021 13:34:38

Generated On: 11 Aug 2021 22:35:20

	Intraocular	<input type="checkbox"/>
	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)	08 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Mar 2021 13:34:38

Generated On: 11 Aug 2021 22:35:20

Name of Medication FLEXERIL

Prophylaxis Yes ☐
No ☒

Indication AE IDIOPATHIC PLEURISY
WITH RECURRENCE

Dose per administration 5

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Mar 2021 13:34:38

Generated On: 11 Aug 2021 22:35:20

	Intraocular	<input type="checkbox"/>
	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)	2 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Mar 2021 13:34:38

Generated On: 11 Aug 2021 22:35:20

Name of Medication ALBUTEROL

Prophylaxis Yes ☐
No ☒

Indication AE IDIOPATHIC PLEURISY
WITH RECURRENCE

Dose per administration 1.25

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Mar 2021 13:34:38

Generated On: 11 Aug 2021 22:35:20

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" 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)		2 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 22 Mar 2021 13:34:38

Generated On: 11 Aug 2021 22:35:20

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication WELLNESS

Dose per administration 0.5

Dose unit mg ☐
ug ☐
mL ☒
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☒
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 22 Mar 2021 13:34:38

Generated On: 11 Aug 2021 22:35:20

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		21 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		21 OCT 2020
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"/>

US3342253

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 22 Mar 2021 13:34:39

Generated On: 11 Aug 2021 22:35:20

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3342253

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 29 Mar 2021 15:31:31

Generated On: 11 Aug 2021 22:35:20

Date of dosing discontinuation (dd MMM yyyy)	13 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	AE #1
---	-------

US3342253

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:35:20

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

US3342253 (Prod: Tekton Research- Austin)

US3342253

Form: Participant Creation

Generated On: 11 Aug 2021 22:35:20

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:15:18
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
User entered 'US3342253'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 21:04:35

US3342253

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:35:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:16:22
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 21:43:11

US3342253

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:16:22
User entered '11 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 21:04:36

US3342253

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:16:22
User entered 'Clinic (Clinic)'	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 21:43:11

US3342253

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:35:20

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User entered 'SCRN'	System	11 Sep 2020 21:43:11

US3342253

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:35:20

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:23:46
User entered (b) (6) 1996'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 21:04:37

US3342253

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:35:20

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:23:46
User entered '24'	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 21:43:51

US3342253

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:35:20

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User entered 'YEARS'	System	11 Sep 2020 21:43:51

US3342253

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:35:20

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User entered '24'	System	11 Sep 2020 21:44:01

US3342253

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:35:20

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:23:46
User entered 'Male (M)'	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 21:43:51

US3342253

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:35:20

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:23:46
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 21:43:51

US3342253

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:35:20

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:23:46
User entered 'l'	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 21:43:51

US3342253

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:35:20

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:23:46
User entered '0'	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 21:43:51

US3342253

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:35:20

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:23:46
User entered '0'	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 21:43:51

US3342253

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:35:20

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:23:46
User entered '0'	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 21:43:51

US3342253

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:35:20

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:23:46
User entered '0'	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 21:43:51

US3342253

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:35:20

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:23:46
User entered '0'	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 21:43:51

US3342253

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:35:20

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:23:46
User entered empty.	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 21:43:51

US3342253

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:35:20

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:23:46
User entered '0'	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 21:43:51

US3342253

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:35:20

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:23:46
User entered '0'	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 21:43:51

US3342253

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:35:20

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:23:41
User entered '11 Sep 2020'	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 21:44:01

US3342253

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User entered 'Sep 2020'	System	11 Sep 2020 21:44:01

US3342253

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User entered '2020'	System	11 Sep 2020 21:44:01

US3342253

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:35:20

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:23:41
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 21:44:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Sep 2020 21:44:08
User entered 'Amendment 3 (3)' reason for change: Data Entry Error	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 21:44:08
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 21:44:01
User entered empty.	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 21:44:01

US3342253

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:23:41
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 21:44:01

US3342253

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:35:20

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:23:41
User entered empty.	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 21:44:01

US3342253

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:35:20

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:23:41
User entered empty.	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 21:44:01

US3342253

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:35:20

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:23:41
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 21:44:01

US3342253

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:35:20

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:23:41
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 21:04:36

US3342253

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:35:20

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User entered 'I'	System	11 Sep 2020 21:44:11

US3342253

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:23:33
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 21:44:11

US3342253

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:35:20

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:23:25
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 21:44:44

US3342253

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:35:20

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:23:20
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Pleural disorders, HLT: Pleural infections and inflammations, PT: Pleurisy, LLT: Pleurisy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 22:22:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 22:22:40
Data point term sent to Coder	System	11 Sep 2020 22:21:11
User entered 'PLEURISY'	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 22:20:24

US3342253

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:23:20
User entered 'UN Oct 2019'	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 22:20:24

US3342253

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:35:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:23:20
User entered '0'	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 22:20:24

US3342253

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:35:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:23:20
Query 'Per DM CLR: Please review the status of this acute MH as the duration is unexpected for this medical condition. Please review and confirm if it is ongoing upon study entry. If not, add a stop date if appropriate or provide explanation for the Med History duration. ' canceled (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 12:46:42
User opened query 'Per DM CLR: Please review the status of this acute MH as the duration is unexpected for this medical condition. Please review and confirm if it is ongoing upon study entry. If not, add a stop date if appropriate or provide explanation for the Med History duration. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 15:38:08
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 22:20:24

US3342253

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:23:20
User entered empty.	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 22:20:24

US3342253

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:35:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:23:20
User entered '0'	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 22:20:24

US3342253

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User entered 'Oct 2019'	System	11 Sep 2020 22:20:24

US3342253

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:35:20

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User entered '2019'	System	11 Sep 2020 22:20:24

US3342253

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User entered empty.	System	11 Sep 2020 22:20:24

US3342253

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User entered empty.	System	11 Sep 2020 22:20:24

US3342253

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:23:01
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 21:45:21

US3342253

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:23:01
User entered '11 Sep 2020'	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 21:45:21

US3342253

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:23:01
User entered '15:54'	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 21:45:21

US3342253

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User entered '11 Sep 2020 15:54'	System	11 Sep 2020 21:45:21

US3342253

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:20

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:23:01
User entered '180.0' cm	Morgan Schulle (b) (4)	11 Sep 2020 21:45:21
DataPoint set to visible.	(b) (4) System	11 Sep 2020 21:44:11

US3342253

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:23:01
User entered '85.8' kg	Morgan Schulle (b) (4)	11 Sep 2020 21:45:21
DataPoint set to visible.	(b) (4) System	11 Sep 2020 21:44:11

US3342253

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:20

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User entered '26.48148'	System	11 Sep 2020 21:45:21
DataPoint set to visible.	System	11 Sep 2020 21:44:11

US3342253

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:20

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User entered 'kg/m2'	System	11 Sep 2020 21:45:21
DataPoint set to visible.	System	11 Sep 2020 21:44:11

US3342253

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:23:01
User entered missing code ND - Not Done.	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 21:45:21

US3342253

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:23:01
User entered empty.	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 21:45:21

US3342253

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:23:01
User entered empty.	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 21:45:21

US3342253

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:23:01
User entered missing code ND - Not Done.	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 21:45:21

US3342253

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User entered 'bpm'	System	11 Sep 2020 21:45:21

US3342253

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:23:01
User entered missing code ND - Not Done.	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 21:45:21

US3342253

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User entered 'breaths/min'	System	11 Sep 2020 21:45:21

US3342253

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:23:01
User entered missing code ND - Not Done.	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 21:45:21

US3342253

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User entered 'mmHg'	System	11 Sep 2020 21:45:21

US3342253

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:23:01
User entered missing code ND - Not Done.	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 21:45:21

US3342253

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:20

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User entered 'mmHg'	System	11 Sep 2020 21:45:21

US3342253

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:20

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47

US3342253

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:20

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47

US3342253

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:22:04
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 21:45:33

US3342253

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:20

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:22:04
User entered '11 Sep 2020'	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 21:45:33

US3342253

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:24:44
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 21:45:56

US3342253

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:24:44
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 21:45:56

US3342253

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:20

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)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:24:44
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 21:45:56

US3342253

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:20

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)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:24:44
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 21:45:56

US3342253

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:24:44
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 21:45:56

US3342253

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:20

[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)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:24:44
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 21:45:56

US3342253

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:20

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)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:24:44
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 21:45:56

US3342253

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:20

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)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:24:44
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 21:45:56

US3342253

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:20

[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)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:24:44
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 21:45:56

US3342253

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:20

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)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:24:44
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 21:45:56

US3342253

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:20

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)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:24:44
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 21:45:56

US3342253

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:20

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:24:44
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 21:45:56

US3342253

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:20

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:24:44
User entered empty.	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 21:45:56

US3342253

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:20

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
User entered '0'	Morgan Schulle (b) (4)	11 Sep 2020 21:45:56

US3342253

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:24:44
User entered '0'	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 21:45:56

US3342253

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:20

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)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:24:44
User entered '0'	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 21:45:56

US3342253

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:20

[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)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:24:44
User entered '0'	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 21:45:56

US3342253

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:20

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)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:24:44
User entered 'I'	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 21:45:56

US3342253

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:24:44
User entered '0'	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 21:45:56

US3342253

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:20

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
User entered '0'	Morgan Schulle (b) (4)	11 Sep 2020 21:45:56

US3342253

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:20

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:48:47
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:24:44
User entered empty.	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 21:45:56

US3342253

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:35:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:24:54
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 22:20:35

US3342253

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:24:54
User entered '11 Sep 2020'	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 22:20:35

US3342253

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:24:54
User entered 'Clinic (Clinic)'	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 22:20:35

US3342253

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:35:20

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User entered 'VISIT1'	System	11 Sep 2020 22:20:35

US3342253

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:26:01
User entered '11 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 21:29:18

US3342253

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:26:01
User entered '146309'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 21:29:18

US3342253

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:26:01
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 21:29:18

US3342253

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:35:20

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)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:26:01
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 21:47:06

US3342253

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:35:20

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)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:26:01
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 21:47:06

US3342253

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:26:01
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 21:47:06

US3342253

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:35:20

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:26:01
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 21:47:06

US3342253

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:35:20

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:26:01
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 21:47:06

US3342253

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:26:01
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 17:36:52
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 09:04:08
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 09:04:07

US3342253

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:35:20

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:26:07
User entered missing code ND - Not Done.	(b) (4), (b) (6)	11 Sep 2020 22:24:12

US3342253

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:35:20

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:26:07
User entered missing code ND - Not Done.	(b) (4), (b) (6)	11 Sep 2020 22:24:12

US3342253

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:35:20

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:26:07
User entered missing code ND - Not Done.	(b) (4), (b) (6)	11 Sep 2020 22:24:12

US3342253

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:35:20

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:26:07
User entered missing code ND - Not Done.	(b) (4), (b) (6)	11 Sep 2020 22:24:12

US3342253

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:20

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	11 Sep 2020 22:24:12

US3342253

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:26:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 22:24:12

US3342253

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:26:07
User entered '11 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 22:24:12

US3342253

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:26:07
User entered '15:54'	(b) (4), (b) (6)	11 Sep 2020 22:24:12

US3342253

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User entered '11 Sep 2020 15:54'	System	11 Sep 2020 22:24:12

US3342253

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:26:07
User entered '97.9' F	(b) (4), (b) (6)	11 Sep 2020 22:24:12

US3342253

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:26:07
User entered 'Oral (Oral)'	(b) (4), (b) (6)	11 Sep 2020 22:24:12

US3342253

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:26:07
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 22:24:12

US3342253

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:26:07
User entered '71'	(b) (4), (b) (6)	11 Sep 2020 22:24:12

US3342253

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User entered 'bpm'	System	11 Sep 2020 22:24:12

US3342253

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:26:07
User entered '14'	(b) (4), (b) (6)	11 Sep 2020 22:24:12

US3342253

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User entered 'breaths/min'	System	11 Sep 2020 22:24:12

US3342253

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:26:07
User entered '127'	(b) (4), (b) (6)	11 Sep 2020 22:24:12

US3342253

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User entered 'mmHg'	System	11 Sep 2020 22:24:12

US3342253

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:26:07
User entered '72'	(b) (4), (b) (6)	11 Sep 2020 22:24:12

US3342253

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:20

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User entered 'mmHg'	System	11 Sep 2020 22:24:12

US3342253

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:35:20

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:26:07
User entered missing code ND - Not Done.	(b) (4), (b) (6)	11 Sep 2020 22:24:12

US3342253

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:35:20

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:26:07
User entered missing code ND - Not Done.	(b) (4), (b) (6)	11 Sep 2020 22:24:12

US3342253

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:20

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	11 Sep 2020 22:24:12

US3342253

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:26:07
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 22:31:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Sep 2020 22:31:44
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 22:31:44
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 22:24:12
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 22:24:12

US3342253

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:26:07
User entered '11 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 22:31:44
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 22:24:12

US3342253

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:26:07
User closed query 'Post-dose Time is prior to Pre-dose Time. Please review and reconcile.' (Site from System).	System	18 Sep 2020 14:46:02
User entered '17:26' reason for change: Data Entry Error	Morgan Schulle (b) (4) (b) (4)	18 Sep 2020 14:46:02
User opened query 'Post-dose Time is prior to Pre-dose Time. Please review and reconcile.' (Site from System).	System	11 Sep 2020 22:31:44
User entered '15:26' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 22:31:44
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 22:24:12

US3342253

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User entered '11 Sep 2020 17:26'	System	18 Sep 2020 14:46:02
User entered '11 Sep 2020 15:26'	System	11 Sep 2020 22:31:44
User entered empty.	System	11 Sep 2020 22:24:12

US3342253

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:26:07
User entered '97.7' F reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 22:31:44
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 22:24:12

US3342253

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:26:07
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 22:31:44
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 22:24:12

US3342253

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:26:07
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 22:24:12

US3342253

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:26:07
User entered '58' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 22:31:44
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 22:24:12

US3342253

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User entered 'bpm'	System	11 Sep 2020 22:31:44
User entered empty.	System	11 Sep 2020 22:24:12

US3342253

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:26:07
User entered '14' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 22:31:44
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 22:24:12

US3342253

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User entered 'breaths/min'	System	11 Sep 2020 22:31:44
User entered empty.	System	11 Sep 2020 22:24:12

US3342253

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:26:07
User entered '108' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 22:31:44
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 22:24:12

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User entered 'mmHg'	System	11 Sep 2020 22:31:44
User entered empty.	System	11 Sep 2020 22:24:12

US3342253

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:26:07
User entered '67' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 22:31:44
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 22:24:12

US3342253

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:20

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User entered 'mmHg'	System	11 Sep 2020 22:31:44
User entered empty.	System	11 Sep 2020 22:24:12

US3342253

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:21:54
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 22:21:14

US3342253

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:20

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:21:54
User entered empty.	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 22:21:14

US3342253

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:35:20

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:18:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 22:20:22

US3342253

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:35:20

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:18:36
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 22:20:22

US3342253

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:35:20

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)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:18:36
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 22:20:22

US3342253

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:35:20

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User entered 'MRNA-1273 OR PLACEBO'	System	11 Sep 2020 22:20:22

US3342253

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:35:20

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:18:36
User entered '11 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 22:20:22

US3342253

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:18:36
User entered '16:55'	(b) (4), (b) (6)	11 Sep 2020 22:20:22

US3342253

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User entered '11 Sep 2020 16:55'	System	11 Sep 2020 22:20:22

US3342253

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:18:36
User entered 'Right Arm (RIGHT ARM)'	(b) (4), (b) (6)	11 Sep 2020 22:20:22

US3342253

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 07:18:36
User entered 'ONCE'	System	11 Sep 2020 22:20:22

US3342253

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:35:20

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User entered 'INTRAMUSCULAR'	System	11 Sep 2020 22:20:22

US3342253

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:19:34
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 22:21:48

US3342253

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:20

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:19:34
User entered '11 Sep 2020'	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 22:21:48

US3342253

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:20

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:19:34
User closed query 'Data is required. Please provide.' (Site from System).	System	24 Sep 2020 16:17:06
User entered '16:45' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 16:17:06
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Sep 2020 22:21:48
User entered empty.	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 22:21:48

US3342253

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User entered '11 Sep 2020 16:45'	System	24 Sep 2020 16:17:06
User entered empty.	System	11 Sep 2020 22:21:48

US3342253

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:35:20

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:20:02
User entered '11 Sep 2020'	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 22:21:58

US3342253

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:35:20

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 22:21:58

US3342253

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:35:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:20:02
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 22:21:58

US3342253

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:35:20

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:20:02
User closed query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	24 Sep 2020 16:18:08
Query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' answered by data change (Site from System).	System	24 Sep 2020 16:18:08
User entered '16:46' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 16:18:08
User opened query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	11 Sep 2020 22:21:58
User entered empty.	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 22:21:58

US3342253

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:35:20

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User entered '11 Sep 2020 16:46'	System	24 Sep 2020 16:18:08
User entered empty.	System	11 Sep 2020 22:21:58

US3342253

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:35:20

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 22:21:58

US3342253

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:35:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:20:02
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 22:21:58

US3342253

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:35:20

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:20:02
User entered empty.	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 22:21:58

US3342253

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:35:20

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User entered empty.	System	11 Sep 2020 22:21:58

US3342253

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:18:20
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 22:22:03

US3342253

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:35:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User entered '1'	System	11 Sep 2020 22:22:03

US3342253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
Data entry locked.	System	11 Sep 2020 22:20:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:35:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-11T17:31:13', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '29d44427-1c4c-45bc-b30e-58ffbaab993b' User entered 'Yes (Y)'	System	11 Sep 2020 22:31:36
	System	11 Sep 2020 22:31:36

US3342253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:35:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-11T17:31:19', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '29d44427-1c4c-45bc-b30e-58ffbaab993b' User entered '97.7'	System	11 Sep 2020 22:31:36
	System	11 Sep 2020 22:31:36

US3342253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-11T17:31:22', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '29d44427-1c4c-45bc-b30e-58ffbaab993b' User entered 'No (N)'	System	11 Sep 2020 22:31:36
	System	11 Sep 2020 22:31:36

US3342253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:35:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-11T17:31:27', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '29d44427-1c4c-45bc-b30e-58ffbaab993b' User entered '11 Sep 2020 17:31'	System	11 Sep 2020 22:31:36
	System	11 Sep 2020 22:31:36

US3342253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:35:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
User entered '11 Sep 2020 17:15'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:35:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
User entered '11 Sep 2020 19:45'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
Data entry locked.	System	11 Sep 2020 22:20:22
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:35:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-11T21:12:40', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '71acbb48-0bba-40bc-95dc-dd77c475a95f' User entered 'Yes (Y)'	System	12 Sep 2020 02:12:58
	System	12 Sep 2020 02:12:58

US3342253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:35:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-11T21:12:45', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '71acbb48-0bba-40bc-95dc-dd77c475a95f' User entered '97.1'	System	12 Sep 2020 02:12:58
	System	12 Sep 2020 02:12:58

US3342253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-11T21:12:49', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '71acbb48-0bba-40bc-95dc-dd77c475a95f' User entered 'No (N)'	System	12 Sep 2020 02:12:58
	System	12 Sep 2020 02:12:58

US3342253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:35:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-11T21:12:52', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '71acbb48-0bba-40bc-95dc-dd77c475a95f' User entered '11 Sep 2020 21:12'	System	12 Sep 2020 02:12:58
	System	12 Sep 2020 02:12:58

US3342253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:35:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
User entered '11 Sep 2020 20:40'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:35:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
Data entry locked.	System	11 Sep 2020 22:20:22
User entered 'Day 2'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:35:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-12T17:40:05', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '4bfa0c2b-d6e4-4a1b-81bf-7078754b2645'	System	12 Sep 2020 22:40:18
User entered 'Yes (Y)'	System	12 Sep 2020 22:40:18

US3342253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:35:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-12T17:40:09', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '4bfa0c2b-d6e4-4a1b-81bf-7078754b2645' User entered '98.0'	System	12 Sep 2020 22:40:18
	System	12 Sep 2020 22:40:18

US3342253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-12T17:40:13', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '4bfa0c2b-d6e4-4a1b-81bf-7078754b2645'	System	12 Sep 2020 22:40:18
User entered 'No (N)'	System	12 Sep 2020 22:40:18

US3342253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:35:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-12T17:40:16', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '4bfa0c2b-d6e4-4a1b-81bf-7078754b2645'	System	12 Sep 2020 22:40:18
User entered '12 Sep 2020 17:40'	System	12 Sep 2020 22:40:18

US3342253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:35:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:35:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
Data entry locked.	System	11 Sep 2020 22:20:22
User entered 'Day 3'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:35:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-13T17:26:20', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'c4f39592-855a-405b-abb0-9648e9eab1f0' User entered 'Yes (Y)'	System	13 Sep 2020 22:26:33
	System	13 Sep 2020 22:26:33

US3342253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:35:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-13T17:26:24', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'c4f39592-855a-405b-abb0-9648e9eab1f0' User entered '96.5'	System	13 Sep 2020 22:26:33
	System	13 Sep 2020 22:26:33

US3342253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-13T17:26:27', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'c4f39592-855a-405b-abb0-9648e9eab1f0' User entered 'No (N)'	System	13 Sep 2020 22:26:33
	System	13 Sep 2020 22:26:33

US3342253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:35:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-13T17:26:29', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'c4f39592-855a-405b-abb0-9648e9eab1f0' User entered '13 Sep 2020 17:26'	System	13 Sep 2020 22:26:33
	System	13 Sep 2020 22:26:33

US3342253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:35:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:35:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
Data entry locked.	System	11 Sep 2020 22:20:22
User entered 'Day 4'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:35:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-14T19:12:12', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '7d385c66-d8ac-4604-85da-874bac99e090' User entered 'Yes (Y)'	System	15 Sep 2020 00:12:22
	System	15 Sep 2020 00:12:22

US3342253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:35:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-14T19:12:16', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '7d385c66-d8ac-4604-85da-874bac99e090' User entered '96.8'	System	15 Sep 2020 00:12:22
	System	15 Sep 2020 00:12:22

US3342253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-14T19:12:18', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '7d385c66-d8ac-4604-85da-874bac99e090' User entered 'No (N)'	System	15 Sep 2020 00:12:22
	System	15 Sep 2020 00:12:22

US3342253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:35:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-14T19:12:20', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '7d385c66-d8ac-4604-85da-874bac99e090' User entered '14 Sep 2020 19:12'	System	15 Sep 2020 00:12:22
	System	15 Sep 2020 00:12:22

US3342253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:35:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:35:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
Data entry locked.	System	11 Sep 2020 22:20:22
User entered 'Day 5'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:35:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-15T19:26:28', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '3dc0d624-45f9-450c-a9c7-b0dff0126314' User entered 'Yes (Y)'	System	16 Sep 2020 00:26:41
	System	16 Sep 2020 00:26:41

US3342253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:35:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-15T19:26:32', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '3dc0d624-45f9-450c-a9c7-b0dff0126314' User entered '97.1'	System	16 Sep 2020 00:26:41
	System	16 Sep 2020 00:26:41

US3342253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-15T19:26:35', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '3dc0d624-45f9-450c-a9c7-b0dff0126314' User entered 'No (N)'	System	16 Sep 2020 00:26:41
	System	16 Sep 2020 00:26:41

US3342253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:35:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-15T19:26:37', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '3dc0d624-45f9-450c-a9c7-b0dff0126314' User entered '15 Sep 2020 19:26'	System	16 Sep 2020 00:26:41
	System	16 Sep 2020 00:26:41

US3342253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:35:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:35:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
Data entry locked.	System	11 Sep 2020 22:20:22
User entered 'Day 6'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:35:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-16T18:44:38', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '1ab8e85f-780f-4f37-8b64-378c4561014c' User entered 'Yes (Y)'	System	16 Sep 2020 23:44:47
	System	16 Sep 2020 23:44:47

US3342253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:35:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-16T18:44:41', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '1ab8e85f-780f-4f37-8b64-378c4561014c' User entered '97.4'	System	16 Sep 2020 23:44:47
	System	16 Sep 2020 23:44:47

US3342253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-16T18:44:43', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '1ab8e85f-780f-4f37-8b64-378c4561014c' User entered 'No (N)'	System	16 Sep 2020 23:44:47
	System	16 Sep 2020 23:44:47

US3342253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:35:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-16T18:44:45', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '1ab8e85f-780f-4f37-8b64-378c4561014c' User entered '16 Sep 2020 18:44'	System	16 Sep 2020 23:44:47
	System	16 Sep 2020 23:44:47

US3342253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:35:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:35:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
Data entry locked.	System	11 Sep 2020 22:20:22
User entered 'Day 7'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:35:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-17T18:12:12', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'ae12abb3-fe1c-417d-a061-f52380478a3a' User entered 'Yes (Y)'	System	17 Sep 2020 23:12:25
	System	17 Sep 2020 23:12:25

US3342253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:35:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-17T18:12:15', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'ae12abb3-fe1c-417d-a061-f52380478a3a' User entered '96.3'	System	17 Sep 2020 23:12:25
	System	17 Sep 2020 23:12:25

US3342253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-17T18:12:18', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'ae12abb3-fe1c-417d-a061-f52380478a3a' User entered 'No (N)'	System	17 Sep 2020 23:12:25
	System	17 Sep 2020 23:12:25

US3342253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:35:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-17T18:12:20', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'ae12abb3-fe1c-417d-a061-f52380478a3a' User entered '17 Sep 2020 18:12'	System	17 Sep 2020 23:12:25
	System	17 Sep 2020 23:12:25

US3342253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:35:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:35:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
Data entry locked.	System	11 Sep 2020 22:20:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:35:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-11T17:31:37', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '5bc2faca-13a6-47a7-879f-28449fe76f0b' User entered 'None (1)'	System	11 Sep 2020 22:32:54
	System	11 Sep 2020 22:32:54

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:35:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-11T17:31:56', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '5bc2faca-13a6-47a7-879f-28449fe76f0b' User entered 'No (N)'	System	11 Sep 2020 22:32:54
	System	11 Sep 2020 22:32:54

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-11T17:31:58', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '5bc2faca-13a6-47a7-879f-28449fe76f0b' User entered 'No (N)'	System	11 Sep 2020 22:32:54
	System	11 Sep 2020 22:32:54

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:35:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-11T17:32:21', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '5bc2faca-13a6-47a7-879f-28449fe76f0b' User entered 'None (1)'	System	11 Sep 2020 22:32:54
	System	11 Sep 2020 22:32:54

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:35:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-11T17:32:28', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '5bc2faca-13a6-47a7-879f-28449fe76f0b' User entered '11 Sep 2020 17:32'	System	11 Sep 2020 22:32:54
	System	11 Sep 2020 22:32:54

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:35:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
User entered '11 Sep 2020 17:15'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:35:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
User entered '11 Sep 2020 19:45'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
Data entry locked.	System	11 Sep 2020 22:20:22
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:35:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-11T21:12:56', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'e8f939a6-c8e3-45fa-9584-3be633628fa7' User entered 'None (1)'	System	12 Sep 2020 02:13:23
	System	12 Sep 2020 02:13:23

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-11T21:12:59', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'e8f939a6-c8e3-45fa-9584-3be633628fa7' User entered 'No (N)'	System	12 Sep 2020 02:13:23
	System	12 Sep 2020 02:13:23

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-11T21:13:12', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'e8f939a6-c8e3-45fa-9584-3be633628fa7' User entered 'No (N)'	System	12 Sep 2020 02:13:23
	System	12 Sep 2020 02:13:23

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:35:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-11T21:13:16', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'e8f939a6-c8e3-45fa-9584-3be633628fa7' User entered 'None (1)'	System	12 Sep 2020 02:13:23
	System	12 Sep 2020 02:13:23

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:35:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-11T21:13:19', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'e8f939a6-c8e3-45fa-9584-3be633628fa7' User entered '11 Sep 2020 21:13'	System	12 Sep 2020 02:13:23
	System	12 Sep 2020 02:13:23

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:35:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
User entered '11 Sep 2020 20:40'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:35:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
Data entry locked.	System	11 Sep 2020 22:20:22
User entered 'Day 2'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:35:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-12T17:40:20', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '40901a07-df81-4ec0-ab1a-964a433d8148' User entered 'None (1)'	System	12 Sep 2020 22:40:33
	System	12 Sep 2020 22:40:33

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:35:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-12T17:40:22', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '40901a07-df81-4ec0-ab1a-964a433d8148' User entered 'No (N)'	System	12 Sep 2020 22:40:33
	System	12 Sep 2020 22:40:33

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-12T17:40:24', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '40901a07-df81-4ec0-ab1a-964a433d8148' User entered 'No (N)'	System	12 Sep 2020 22:40:33
	System	12 Sep 2020 22:40:33

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:35:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-12T17:40:26', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '40901a07-df81-4ec0-ab1a-964a433d8148' User entered 'None (1)'	System	12 Sep 2020 22:40:33
	System	12 Sep 2020 22:40:33

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:35:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-12T17:40:28', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '40901a07-df81-4ec0-ab1a-964a433d8148' User entered '12 Sep 2020 17:40'	System	12 Sep 2020 22:40:33
	System	12 Sep 2020 22:40:33

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:35:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:35:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
Data entry locked.	System	11 Sep 2020 22:20:22
User entered 'Day 3'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:35:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-13T17:26:33', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '52f492c7-8213-497f-bb46-afcf3ae729e'	System	13 Sep 2020 22:26:53
User entered 'None (1)'	System	13 Sep 2020 22:26:53

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:35:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-13T17:26:35', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '52f492c7-8213-497f-bb46-afcf3ae729e'	System	13 Sep 2020 22:26:53
User entered 'No (N)'	System	13 Sep 2020 22:26:53

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-13T17:26:38', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '52f492c7-8213-497f-bb46-afcf3ae729e' User entered 'No (N)'	System	13 Sep 2020 22:26:53
	System	13 Sep 2020 22:26:53

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:35:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-13T17:26:42', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '52f492c7-8213-497f-bb46-afcf3ae729e'	System	13 Sep 2020 22:26:53
User entered 'None (1)'	System	13 Sep 2020 22:26:53

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:35:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-13T17:26:51', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '52f492c7-8213-497f-bb46-afcf3ae729e' User entered '13 Sep 2020 17:26'	System	13 Sep 2020 22:26:53
	System	13 Sep 2020 22:26:53

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:35:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:35:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
Data entry locked.	System	11 Sep 2020 22:20:22
User entered 'Day 4'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:35:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-14T19:12:23', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'e9329d24-06be-4734-974a-12bdc3f3a673' User entered 'None (1)'	System	15 Sep 2020 00:12:35
	System	15 Sep 2020 00:12:35

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:35:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-14T19:12:25', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'e9329d24-06be-4734-974a-12bdc3f3a673' User entered 'No (N)'	System	15 Sep 2020 00:12:35
	System	15 Sep 2020 00:12:35

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-14T19:12:27', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'e9329d24-06be-4734-974a-12bdc3f3a673' User entered 'No (N)'	System	15 Sep 2020 00:12:35
	System	15 Sep 2020 00:12:35

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:35:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-14T19:12:29', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'e9329d24-06be-4734-974a-12bdc3f3a673' User entered 'None (1)'	System	15 Sep 2020 00:12:35
	System	15 Sep 2020 00:12:35

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:35:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-14T19:12:31', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'e9329d24-06be-4734-974a-12bdc3f3a673' User entered '14 Sep 2020 19:12'	System	15 Sep 2020 00:12:35
	System	15 Sep 2020 00:12:35

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:35:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:35:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
Data entry locked.	System	11 Sep 2020 22:20:22
User entered 'Day 5'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:35:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-15T19:26:40', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'f5c4e502-aad9-49dc-b44e-8c9d768f58e6' User entered 'None (1)'	System	16 Sep 2020 00:26:50
	System	16 Sep 2020 00:26:50

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:35:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-15T19:26:43', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'f5c4e502-aad9-49dc-b44e-8c9d768f58e6' User entered 'No (N)'	System	16 Sep 2020 00:26:50
	System	16 Sep 2020 00:26:50

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-15T19:26:44', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'f5c4e502-aad9-49dc-b44e-8c9d768f58e6' User entered 'No (N)'	System	16 Sep 2020 00:26:50
	System	16 Sep 2020 00:26:50

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:35:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-15T19:26:45', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'f5c4e502-aad9-49dc-b44e-8c9d768f58e6' User entered 'None (1)'	System	16 Sep 2020 00:26:50
	System	16 Sep 2020 00:26:50

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:35:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-15T19:26:47', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'f5c4e502-aad9-49dc-b44e-8c9d768f58e6' User entered '15 Sep 2020 19:26'	System	16 Sep 2020 00:26:50
	System	16 Sep 2020 00:26:50

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:35:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:35:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
Data entry locked.	System	11 Sep 2020 22:20:22
User entered 'Day 6'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:35:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-16T18:44:59', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '609cfbe1-7a69-42b5-a776-e9fb38c9d527'	System	16 Sep 2020 23:45:08
User entered 'None (1)'	System	16 Sep 2020 23:45:08

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:35:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-16T18:45:00', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '609cfbe1-7a69-42b5-a776-e9fb38c9d527' User entered 'No (N)'	System	16 Sep 2020 23:45:08
	System	16 Sep 2020 23:45:08

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-16T18:45:02', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '609cfbe1-7a69-42b5-a776-e9fb38c9d527' User entered 'No (N)'	System	16 Sep 2020 23:45:08
	System	16 Sep 2020 23:45:08

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:35:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-16T18:45:03', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '609cfbe1-7a69-42b5-a776-e9fb38c9d527'	System	16 Sep 2020 23:45:08
User entered 'None (1)'	System	16 Sep 2020 23:45:08

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:35:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-16T18:45:04', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '609cfbe1-7a69-42b5-a776-e9fb38c9d527'	System	16 Sep 2020 23:45:08
User entered '16 Sep 2020 18:45'	System	16 Sep 2020 23:45:08

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:35:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:35:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
Data entry locked.	System	11 Sep 2020 22:20:22
User entered 'Day 7'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:35:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-17T18:11:43', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '449fb6b2-ebfc-47f4-ac73-40a4af51e300'	System	17 Sep 2020 23:12:01
User entered 'None (1)'	System	17 Sep 2020 23:12:01

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:35:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-17T18:11:45', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '449fb6b2-ebfc-47f4-ac73-40a4af51e300'	System	17 Sep 2020 23:12:01
User entered 'No (N)'	System	17 Sep 2020 23:12:01

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-17T18:11:46', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '449fb6b2-ebfc-47f4-ac73-40a4af51e300'	System	17 Sep 2020 23:12:01
User entered 'No (N)'	System	17 Sep 2020 23:12:01

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:35:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-17T18:11:48', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '449fb6b2-ebfc-47f4-ac73-40a4af51e300'	System	17 Sep 2020 23:12:01
User entered 'None (1)'	System	17 Sep 2020 23:12:01

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:35:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-17T18:11:49', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '449fb6b2-ebfc-47f4-ac73-40a4af51e300' User entered '17 Sep 2020 18:11'	System	17 Sep 2020 23:12:01
	System	17 Sep 2020 23:12:01

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:35:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:35:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
Data entry locked.	System	11 Sep 2020 22:20:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-11T17:32:52', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'e44faeaa-3512-4d7b-8938-21931b6ae13e' User entered 'None (0)'	System	11 Sep 2020 22:33:21
	System	11 Sep 2020 22:33:21

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-11T17:32:58', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'e44faeaa-3512-4d7b-8938-21931b6ae13e' User entered 'None (0)'	System	11 Sep 2020 22:33:21
	System	11 Sep 2020 22:33:21

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-11T17:33:00', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'e44faeaa-3512-4d7b-8938-21931b6ae13e' User entered 'None (0)'	System	11 Sep 2020 22:33:21
	System	11 Sep 2020 22:33:21

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-11T17:33:02', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'e44faeaa-3512-4d7b-8938-21931b6ae13e' User entered 'None (0)'	System	11 Sep 2020 22:33:21
	System	11 Sep 2020 22:33:21

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-11T17:33:04', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'e44faeaa-3512-4d7b-8938-21931b6ae13e' User entered 'None (0)'	System	11 Sep 2020 22:33:21
	System	11 Sep 2020 22:33:21

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-11T17:33:06', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'e44faeaa-3512-4d7b-8938-21931b6ae13e' User entered 'None (0)'	System	11 Sep 2020 22:33:21
	System	11 Sep 2020 22:33:21

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:20

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)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-11T17:33:10', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'e44faeaa-3512-4d7b-8938-21931b6ae13e' User entered 'No (N)'	System	11 Sep 2020 22:33:21
	System	11 Sep 2020 22:33:21

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-11T17:33:14', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'e44faeaa-3512-4d7b-8938-21931b6ae13e' User entered '11 Sep 2020 17:33'	System	11 Sep 2020 22:33:21
	System	11 Sep 2020 22:33:21

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
User entered '11 Sep 2020 17:15'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
User entered '11 Sep 2020 19:45'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
Data entry locked.	System	11 Sep 2020 22:20:22
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-11T21:13:23', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'b68ece73-b168-431c-9b01-b3c81ed5d963' User entered 'None (0)'	System	12 Sep 2020 02:13:44
	System	12 Sep 2020 02:13:44

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-11T21:13:25', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'b68ece73-b168-431c-9b01-b3c81ed5d963' User entered 'None (0)'	System	12 Sep 2020 02:13:44
	System	12 Sep 2020 02:13:44

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-11T21:13:27', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'b68ece73-b168-431c-9b01-b3c81ed5d963' User entered 'None (0)'	System	12 Sep 2020 02:13:44
	System	12 Sep 2020 02:13:44

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-11T21:13:29', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'b68ece73-b168-431c-9b01-b3c81ed5d963' User entered 'None (0)'	System	12 Sep 2020 02:13:44
	System	12 Sep 2020 02:13:44

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-11T21:13:32', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'b68ece73-b168-431c-9b01-b3c81ed5d963' User entered 'None (0)'	System	12 Sep 2020 02:13:44
	System	12 Sep 2020 02:13:44

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-11T21:13:34', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'b68ece73-b168-431c-9b01-b3c81ed5d963' User entered 'None (0)'	System	12 Sep 2020 02:13:44
	System	12 Sep 2020 02:13:44

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:20

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)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-11T21:13:37', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'b68ece73-b168-431c-9b01-b3c81ed5d963' User entered 'No (N)'	System	12 Sep 2020 02:13:44
	System	12 Sep 2020 02:13:44

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-11T21:13:40', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'b68ece73-b168-431c-9b01-b3c81ed5d963' User entered '11 Sep 2020 21:13'	System	12 Sep 2020 02:13:44
	System	12 Sep 2020 02:13:44

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
User entered '11 Sep 2020 20:40'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
Data entry locked.	System	11 Sep 2020 22:20:22
User entered 'Day 2'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-12T17:40:38', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '315fde22-302e-429b-81e4-d069925ad28e'	System	12 Sep 2020 22:41:10
User entered 'No interference with activity (1)'	System	12 Sep 2020 22:41:10

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-12T17:40:41', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '315fde22-302e-429b-81e4-d069925ad28e'	System	12 Sep 2020 22:41:10
User entered 'Some interference with activity (2)'	System	12 Sep 2020 22:41:10

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-12T17:40:46', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '315fde22-302e-429b-81e4-d069925ad28e' User entered 'Some interference with activity (2)'	System	12 Sep 2020 22:41:10
	System	12 Sep 2020 22:41:10

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-12T17:40:49', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '315fde22-302e-429b-81e4-d069925ad28e' User entered 'None (0)'	System	12 Sep 2020 22:41:10
	System	12 Sep 2020 22:41:10

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-12T17:40:51', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '315fde22-302e-429b-81e4-d069925ad28e' User entered 'None (0)'	System	12 Sep 2020 22:41:10
	System	12 Sep 2020 22:41:10

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-12T17:41:01', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '315fde22-302e-429b-81e4-d069925ad28e'	System	12 Sep 2020 22:41:10
User entered 'No interference with activity (1)'	System	12 Sep 2020 22:41:10

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:20

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)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-12T17:41:06', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '315fde22-302e-429b-81e4-d069925ad28e' User entered 'No (N)'	System	12 Sep 2020 22:41:10
	System	12 Sep 2020 22:41:10

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-12T17:41:08', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '315fde22-302e-429b-81e4-d069925ad28e' User entered '12 Sep 2020 17:41'	System	12 Sep 2020 22:41:10
	System	12 Sep 2020 22:41:10

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
Data entry locked.	System	11 Sep 2020 22:20:22
User entered 'Day 3'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-13T17:25:48', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'ee94413a-0fbf-4243-ac36-0837f63d3404' User entered 'None (0)'	System	13 Sep 2020 22:26:11
	System	13 Sep 2020 22:26:11

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-13T17:25:50', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'ee94413a-0fbf-4243-ac36-0837f63d3404' User entered 'None (0)'	System	13 Sep 2020 22:26:11
	System	13 Sep 2020 22:26:11

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-13T17:25:52', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'ee94413a-0fbf-4243-ac36-0837f63d3404' User entered 'None (0)'	System	13 Sep 2020 22:26:11
	System	13 Sep 2020 22:26:11

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-13T17:25:57', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'ee94413a-0fbf-4243-ac36-0837f63d3404' User entered 'None (0)'	System	13 Sep 2020 22:26:11
	System	13 Sep 2020 22:26:11

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-13T17:25:59', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'ee94413a-0fbf-4243-ac36-0837f63d3404' User entered 'None (0)'	System	13 Sep 2020 22:26:11
	System	13 Sep 2020 22:26:11

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-13T17:26:01', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'ee94413a-0fbf-4243-ac36-0837f63d3404' User entered 'None (0)'	System	13 Sep 2020 22:26:11
	System	13 Sep 2020 22:26:11

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:20

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)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-13T17:26:05', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'ee94413a-0fbf-4243-ac36-0837f63d3404' User entered 'No (N)'	System	13 Sep 2020 22:26:11
	System	13 Sep 2020 22:26:11

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-13T17:26:09', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'ee94413a-0fbf-4243-ac36-0837f63d3404'	System	13 Sep 2020 22:26:11
User entered '13 Sep 2020 17:26'	System	13 Sep 2020 22:26:11

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
Data entry locked.	System	11 Sep 2020 22:20:22
User entered 'Day 4'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-14T19:12:34', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '7d6db307-5984-4430-a371-8deef829b9f' User entered 'None (0)'	System	15 Sep 2020 00:12:53
	System	15 Sep 2020 00:12:53

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-14T19:12:36', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '7d6db307-5984-4430-a371-8deef829b9f' User entered 'None (0)'	System	15 Sep 2020 00:12:53
	System	15 Sep 2020 00:12:53

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-14T19:12:38', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '7d6db307-5984-4430-a371-8deef829b9f' User entered 'None (0)'	System	15 Sep 2020 00:12:53
	System	15 Sep 2020 00:12:53

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-14T19:12:39', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '7d6db307-5984-4430-a371-8deef829b9f' User entered 'None (0)'	System	15 Sep 2020 00:12:53
	System	15 Sep 2020 00:12:53

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-14T19:12:40', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '7d6db307-5984-4430-a371-8deef829b9f' User entered 'None (0)'	System	15 Sep 2020 00:12:53
	System	15 Sep 2020 00:12:53

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-14T19:12:41', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '7d6db307-5984-4430-a371-8deef829b9f' User entered 'None (0)'	System	15 Sep 2020 00:12:53
	System	15 Sep 2020 00:12:53

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:20

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)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-14T19:12:45', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '7d6db307-5984-4430-a371-8deef829b9f' User entered 'No (N)'	System	15 Sep 2020 00:12:53
	System	15 Sep 2020 00:12:53

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-14T19:12:49', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '7d6db307-5984-4430-a371-8deef829b9f' User entered '14 Sep 2020 19:12'	System	15 Sep 2020 00:12:53
	System	15 Sep 2020 00:12:53

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
Data entry locked.	System	11 Sep 2020 22:20:22
User entered 'Day 5'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-15T19:26:50', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '45c2f992-6f32-49af-86f6-bd1d4e797dbb' User entered 'None (0)'	System	16 Sep 2020 00:27:07
	System	16 Sep 2020 00:27:07

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-15T19:26:51', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '45c2f992-6f32-49af-86f6-bd1d4e797dbb' User entered 'None (0)'	System	16 Sep 2020 00:27:07
	System	16 Sep 2020 00:27:07

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-15T19:26:53', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '45c2f992-6f32-49af-86f6-bd1d4e797dbb' User entered 'None (0)'	System	16 Sep 2020 00:27:07
	System	16 Sep 2020 00:27:07

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-15T19:26:55', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '45c2f992-6f32-49af-86f6-bd1d4e797dbb' User entered 'None (0)'	System	16 Sep 2020 00:27:07
	System	16 Sep 2020 00:27:07

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-15T19:26:57', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '45c2f992-6f32-49af-86f6-bd1d4e797dbb' User entered 'None (0)'	System	16 Sep 2020 00:27:07
	System	16 Sep 2020 00:27:07

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-15T19:26:58', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '45c2f992-6f32-49af-86f6-bd1d4e797dbb' User entered 'None (0)'	System	16 Sep 2020 00:27:07
	System	16 Sep 2020 00:27:07

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:20

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)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-15T19:27:02', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '45c2f992-6f32-49af-86f6-bd1d4e797dbb' User entered 'No (N)'	System	16 Sep 2020 00:27:07
	System	16 Sep 2020 00:27:07

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-15T19:27:03', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '45c2f992-6f32-49af-86f6-bd1d4e797dbb' User entered '15 Sep 2020 19:27'	System	16 Sep 2020 00:27:07
	System	16 Sep 2020 00:27:07

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
Data entry locked.	System	11 Sep 2020 22:20:22
User entered 'Day 6'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-16T18:44:47', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'fd251c87-43ba-4202-b49a-0402622c4b9e' User entered 'None (0)'	System	16 Sep 2020 23:44:59
	System	16 Sep 2020 23:44:59

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-16T18:44:48', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'fd251c87-43ba-4202-b49a-0402622c4b9e' User entered 'None (0)'	System	16 Sep 2020 23:44:59
	System	16 Sep 2020 23:44:59

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-16T18:44:49', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'fd251c87-43ba-4202-b49a-0402622c4b9e' User entered 'None (0)'	System	16 Sep 2020 23:44:59
	System	16 Sep 2020 23:44:59

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-16T18:44:50', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'fd251c87-43ba-4202-b49a-0402622c4b9e' User entered 'None (0)'	System	16 Sep 2020 23:44:59
	System	16 Sep 2020 23:44:59

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-16T18:44:51', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'fd251c87-43ba-4202-b49a-0402622c4b9e' User entered 'None (0)'	System	16 Sep 2020 23:44:59
	System	16 Sep 2020 23:44:59

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-16T18:44:53', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'fd251c87-43ba-4202-b49a-0402622c4b9e' User entered 'None (0)'	System	16 Sep 2020 23:44:59
	System	16 Sep 2020 23:44:59

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:20

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)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-16T18:44:55', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'fd251c87-43ba-4202-b49a-0402622c4b9e' User entered 'No (N)'	System	16 Sep 2020 23:44:59
	System	16 Sep 2020 23:44:59

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-16T18:44:56', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'fd251c87-43ba-4202-b49a-0402622c4b9e' User entered '16 Sep 2020 18:44'	System	16 Sep 2020 23:44:59
	System	16 Sep 2020 23:44:59

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
Data entry locked.	System	11 Sep 2020 22:20:22
User entered 'Day 7'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-17T18:11:52', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '3cbf7338-5e7f-4432-b278-889dd751a5dc' User entered 'None (0)'	System	17 Sep 2020 23:12:09
	System	17 Sep 2020 23:12:09

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-17T18:11:56', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '3cbf7338-5e7f-4432-b278-889dd751a5dc' User entered 'None (0)'	System	17 Sep 2020 23:12:09
	System	17 Sep 2020 23:12:09

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-17T18:11:57', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '3cbf7338-5e7f-4432-b278-889dd751a5dc' User entered 'None (0)'	System	17 Sep 2020 23:12:09
	System	17 Sep 2020 23:12:09

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-17T18:11:59', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '3cbf7338-5e7f-4432-b278-889dd751a5dc' User entered 'None (0)'	System	17 Sep 2020 23:12:09
	System	17 Sep 2020 23:12:09

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-17T18:12:00', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '3cbf7338-5e7f-4432-b278-889dd751a5dc' User entered 'None (0)'	System	17 Sep 2020 23:12:09
	System	17 Sep 2020 23:12:09

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-17T18:12:02', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '3cbf7338-5e7f-4432-b278-889dd751a5dc' User entered 'None (0)'	System	17 Sep 2020 23:12:09
	System	17 Sep 2020 23:12:09

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:20

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)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-17T18:12:04', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '3cbf7338-5e7f-4432-b278-889dd751a5dc' User entered 'No (N)'	System	17 Sep 2020 23:12:09
	System	17 Sep 2020 23:12:09

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-09-17T18:12:06', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '3cbf7338-5e7f-4432-b278-889dd751a5dc' User entered '17 Sep 2020 18:12'	System	17 Sep 2020 23:12:09
	System	17 Sep 2020 23:12:09

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 22:20:22

US3342253

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 22:20:22

US3342253

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:29:51
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	18 Sep 2020 20:19:12

US3342253

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:20

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:29:51
User entered '18 Sep 2020'	Ethan Shotton (b) (4) (b) (4)	18 Sep 2020 20:19:12

US3342253

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:29:51
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4) (b) (4)	18 Sep 2020 20:19:12

US3342253

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:29:51
User entered empty.	Ethan Shotton (b) (4) (b) (4)	18 Sep 2020 20:19:12

US3342253

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:29:58
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	18 Sep 2020 20:19:16

US3342253

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User entered '1'	System	18 Sep 2020 20:19:16

US3342253

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:28:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 19:59:13

US3342253

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:28:49
User entered '25 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 19:59:13

US3342253

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:28:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	25 Sep 2020 19:59:13

US3342253

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:28:49
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 19:59:13

US3342253

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:28:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 19:59:20

US3342253

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:08:41
User entered 'I'	System	25 Sep 2020 19:59:20

US3342253

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:34
Data entry locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 07:28:00
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	02 Oct 2020 19:16:13

US3342253

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:20

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:34
Data entry locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 07:28:00
User entered '2 Oct 2020'	Ethan Shotton (b) (4)	02 Oct 2020 19:16:13

US3342253

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:34
Data entry locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 07:28:00
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4)	02 Oct 2020 19:16:13

US3342253

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:34
Data entry locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 07:28:00
User entered empty.	Ethan Shotton (b) (4)	02 Oct 2020 19:16:13

US3342253

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:34
Data entry locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 07:28:05
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	02 Oct 2020 19:16:17

US3342253

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:34
Data entry locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:03
User entered 'I'	System	02 Oct 2020 19:16:17

US3342253

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:07:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 17:37:17

US3342253

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:07:17
User entered '13 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 17:37:17

US3342253

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:07:17
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	13 Oct 2020 17:37:17

US3342253

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:20

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User entered 'VISIT2'	System	13 Oct 2020 17:37:17

US3342253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:20

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User accepted default value 'Pre-Dose (PREDOSE)'	John Luna (b) (4)	29 Jan 2021 19:13:55

US3342253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 01:00:58
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
User entered 'Yes (Y)'	John Luna (b) (4)	29 Jan 2021 19:13:55

US3342253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 01:00:58
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
User entered '13 Oct 2020'	John Luna (b) (4)	29 Jan 2021 19:13:55

US3342253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 01:00:58
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
User entered '09:25'	John Luna (b) (4)	29 Jan 2021 19:13:55

US3342253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User entered '13 Oct 2020 09:25'	System	29 Jan 2021 19:13:55

US3342253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 01:00:58
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
User entered '97.9' F	John Luna (b) (4)	29 Jan 2021 19:13:55

US3342253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 01:00:58
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
User entered 'Oral (Oral)'	John Luna (b) (4)	29 Jan 2021 19:13:55

US3342253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 01:00:58
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
User entered empty.	John Luna (b) (4)	29 Jan 2021 19:13:55

US3342253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 01:00:58
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
User entered '76'	John Luna (b) (4)	29 Jan 2021 19:13:55

US3342253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User entered 'bpm'	System	29 Jan 2021 19:13:55

US3342253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 01:00:58
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
User entered '16'	John Luna (b) (4)	29 Jan 2021 19:13:55

US3342253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User entered 'breaths/min'	System	29 Jan 2021 19:13:55

US3342253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 01:00:58
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
User entered '125'	John Luna (b) (4)	29 Jan 2021 19:13:55

US3342253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User entered 'mmHg'	System	29 Jan 2021 19:13:55

US3342253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 01:00:58
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
User entered '86'	(b) (4) John Luna (b) (4)	29 Jan 2021 19:13:55

US3342253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:20

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User entered 'mmHg'	System	29 Jan 2021 19:13:55

US3342253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:20

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User accepted default value 'Post-Dose (POSTDOSE)'	John Luna (b) (4)	29 Jan 2021 19:13:55

US3342253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 01:00:58
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
User entered 'No (N)'	John Luna (b) (4)	29 Jan 2021 19:13:55

US3342253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 01:00:58
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
User entered empty.	John Luna (b) (4)	29 Jan 2021 19:13:55

US3342253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 01:00:58
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
User entered empty.	John Luna (b) (4)	29 Jan 2021 19:13:55

US3342253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User entered empty.	System	29 Jan 2021 19:13:55

US3342253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 01:00:58
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
User entered empty.	John Luna (b) (4)	29 Jan 2021 19:13:55

US3342253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 01:00:58
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
User entered empty.	John Luna (b) (4)	29 Jan 2021 19:13:55

US3342253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 01:00:58
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
User entered empty.	John Luna (b) (4)	29 Jan 2021 19:13:55

US3342253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 01:00:58
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
User entered empty.	John Luna (b) (4)	29 Jan 2021 19:13:55

US3342253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User entered empty.	System	29 Jan 2021 19:13:55

US3342253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 01:00:58
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
User entered empty.	John Luna (b) (4)	29 Jan 2021 19:13:55

US3342253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User entered empty.	System	29 Jan 2021 19:13:55

US3342253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 01:00:58
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
User entered empty.	John Luna (b) (4)	29 Jan 2021 19:13:55

US3342253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User entered empty.	System	29 Jan 2021 19:13:55

US3342253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 01:00:58
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
User entered empty.	John Luna (b) (4)	29 Jan 2021 19:13:55

US3342253

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:20

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User entered empty.	System	29 Jan 2021 19:13:55

US3342253

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 01:01:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 17:37:42

US3342253

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:20

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 01:01:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
User entered '13 Oct 2020'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 17:37:42

US3342253

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:20

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:07:52
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 22:49:30

US3342253

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:20

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:07:52
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)'	(b) (4), (b) (6)	13 Oct 2020 22:49:30

US3342253

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:20

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)	27 Apr 2021 14:10:12
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:07:52
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 22:49:30

US3342253

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:20

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User entered empty.	System	13 Oct 2020 22:49:30

US3342253

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:20

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:07:52
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 22:49:30

US3342253

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:07:52
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 22:49:30

US3342253

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User entered empty.	System	13 Oct 2020 22:49:30

US3342253

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:07:52
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 22:49:30

US3342253

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 07:07:52
User entered empty.	System	13 Oct 2020 22:49:30

US3342253

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:20

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User entered empty.	System	13 Oct 2020 22:49:30

US3342253

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:08:04
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	28 Oct 2020 15:13:18

US3342253

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:20

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:08:04
User entered '13 Oct 2020'	Morgan Schulle (b) (4) (b) (4)	28 Oct 2020 15:13:18

US3342253

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:20

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:08:04
User entered '10:09'	Morgan Schulle (b) (4) (b) (4)	28 Oct 2020 15:13:18

US3342253

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User entered '13 Oct 2020 10:09'	System	28 Oct 2020 15:13:18

US3342253

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:35:20

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 01:01:29
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
User entered '13 Oct 2020'	(b) (4) Morgan Schulle (b) (4) (b) (4)	28 Oct 2020 15:13:32

US3342253

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:35:20

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Morgan Schulle (b) (4) (b) (4)	28 Oct 2020 15:13:32

US3342253

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:35:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 01:01:29
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
User entered 'Yes (Y)'	Morgan Schulle (b) (4)	28 Oct 2020 15:13:32

US3342253

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:35:20

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 01:01:29
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
User entered '10:11'	Morgan Schulle (b) (4)	28 Oct 2020 15:13:32

US3342253

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User entered '13 Oct 2020 10:11'	System	28 Oct 2020 15:13:32

US3342253

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:35:20

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Morgan Schulle (b) (4) (b) (4)	28 Oct 2020 15:13:32

US3342253

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:35:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 01:01:29
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
User entered 'No (N)'	Morgan Schulle (b) (4)	28 Oct 2020 15:13:32

US3342253

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:35:20

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 01:01:29
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
User entered empty.	Morgan Schulle (b) (4)	28 Oct 2020 15:13:32

US3342253

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:35:20

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User entered empty.	System	28 Oct 2020 15:13:32

US3342253

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:09:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 22:49:39

US3342253

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User entered '1'	System	13 Oct 2020 22:49:39

US3342253

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:00:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Oct 2020 15:37:04

US3342253

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:00:49
User entered '22 Oct 2020'	(b) (4), (b) (6)	22 Oct 2020 15:37:04

US3342253

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:00:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	22 Oct 2020 15:37:04

US3342253

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:00:49
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 15:37:04

US3342253

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:00:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Oct 2020 21:19:43

US3342253

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User entered 'I'	System	27 Oct 2020 21:19:43

US3342253

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:01:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Oct 2020 21:20:30

US3342253

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:01:42
User entered '27 Oct 2020'	(b) (4), (b) (6)	27 Oct 2020 21:20:30

US3342253

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:01:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	27 Oct 2020 21:20:30

US3342253

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:01:42
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 21:20:30

US3342253

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:01:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Oct 2020 21:20:36

US3342253

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User entered 'I'	System	27 Oct 2020 21:20:36

US3342253

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:02:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 18:27:44

US3342253

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:02:47
User entered '5 Nov 2020'	(b) (4), (b) (6)	05 Nov 2020 18:27:44

US3342253

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:02:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	05 Nov 2020 18:27:44

US3342253

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:02:47
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 18:27:44

US3342253

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:02:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 18:27:49

US3342253

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User entered 'I'	System	05 Nov 2020 18:27:49

US3342253

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 06:54:48
User entered 'Yes (Y)'	Darrell O'Brien (b) (4) (b) (4)	12 Nov 2020 20:18:59

US3342253

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 06:54:48
User entered '12 Nov 2020'	Darrell O'Brien (b) (4) (b) (4)	12 Nov 2020 20:18:59

US3342253

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 06:54:48
User entered 'Clinic (Clinic)'	Darrell O'Brien (b) (4) (b) (4)	12 Nov 2020 20:18:59

US3342253

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:20

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User entered 'VISIT3'	System	12 Nov 2020 20:18:59

US3342253

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 06:58:44
User entered 'Yes (Y)'	Darrell O'Brien (b) (4) (b) (4)	12 Nov 2020 20:19:34

US3342253

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 06:58:44
User entered '12 Nov 2020'	Darrell O'Brien (b) (4) (b) (4)	12 Nov 2020 20:19:34

US3342253

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 06:58:44
User entered '13:41'	Darrell O'Brien (b) (4) (b) (4)	12 Nov 2020 20:19:34

US3342253

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User entered '12 Nov 2020 13:41'	System	12 Nov 2020 20:19:34

US3342253

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 06:58:44
User entered '98' F	Darrell O'Brien (b) (4) (b) (4)	12 Nov 2020 20:19:34

US3342253

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 06:58:44
User entered 'Oral (Oral)'	Darrell O'Brien (b) (4) (b) (4)	12 Nov 2020 20:19:34

US3342253

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 06:58:44
User entered empty.	Darrell O'Brien (b) (4) (b) (4)	12 Nov 2020 20:19:34

US3342253

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 06:58:44
User entered '71'	Darrell O'Brien (b) (4) (b) (4)	12 Nov 2020 20:19:34

US3342253

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User entered 'bpm'	System	12 Nov 2020 20:19:34

US3342253

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 06:58:44
User entered '12'	Darrell O'Brien (b) (4) (b) (4)	12 Nov 2020 20:19:34

US3342253

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User entered 'breaths/min'	System	12 Nov 2020 20:19:34

US3342253

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 06:58:44
User entered '109'	Darrell O'Brien (b) (4) (b) (4)	12 Nov 2020 20:19:34

US3342253

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User entered 'mmHg'	System	12 Nov 2020 20:19:34

US3342253

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 06:58:44
User entered '76'	Darrell O'Brien (b) (4) (b) (4)	12 Nov 2020 20:19:34

US3342253

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:20

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User entered 'mmHg'	System	12 Nov 2020 20:19:34

US3342253

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:20

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12

US3342253

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:20

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12

US3342253

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 06:58:02
User entered 'No (N)'	Darrell O'Brien (b) (4) (b) (4)	12 Nov 2020 20:19:41

US3342253

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:20

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 06:58:02
User entered empty.	Darrell O'Brien (b) (4) (b) (4)	12 Nov 2020 20:19:41

US3342253

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 06:55:10
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	17 Nov 2020 20:59:01

US3342253

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:20

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 06:55:10
User entered '12 Nov 2020'	Morgan Schulle (b) (4) (b) (4)	17 Nov 2020 20:59:01

US3342253

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:20

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 06:55:10
User entered '14:19'	Morgan Schulle (b) (4) (b) (4)	17 Nov 2020 20:59:01

US3342253

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User entered '12 Nov 2020 14:19'	System	17 Nov 2020 20:59:01

US3342253

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:55:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 06:55:40
User entered 'Yes (Y)'	Darrell O'Brien (b) (4) (b) (4)	12 Nov 2020 20:19:46

US3342253

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User entered 'I'	System	12 Nov 2020 20:19:46

US3342253

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
Data entry locked.	System	11 Sep 2020 22:20:22
User entered 'Day 64'	System	11 Sep 2020 22:20:22

US3342253

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[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)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-11-11T04:12:16', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '59376e4a-0aa3-4c47-9fea-efd4e41fa023' User entered 'No (N)'	System	11 Nov 2020 10:12:36
	System	11 Nov 2020 10:12:36

US3342253

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

Have you been exposed to someone with 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)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-11-11T04:12:28', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '59376e4a-0aa3-4c47-9fea-efd4e41fa023'	System	11 Nov 2020 10:12:36
User entered 'No (N)'	System	11 Nov 2020 10:12:36

US3342253

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-11-11T04:12:32', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '59376e4a-0aa3-4c47-9fea-efd4e41fa023' User entered '11 Nov 2020 04:12:32'	System	11 Nov 2020 10:12:36
	System	11 Nov 2020 10:12:36

US3342253

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
Data entry locked.	System	11 Sep 2020 22:20:22
User entered '11 Nov 2020 00:01'	System	11 Sep 2020 22:20:22

US3342253

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:25:05
Data entry locked.	System	11 Sep 2020 22:20:22
User entered '15 Nov 2020 23:59'	System	11 Sep 2020 22:20:22

US3342253

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:51:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:56:13
Data entry locked.	System	11 Sep 2020 22:20:22
User entered 'Day 71'	System	11 Sep 2020 22:20:22

US3342253

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[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)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:51:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:56:13

US3342253

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Have you been exposed to someone with 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)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:51:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:56:13

US3342253

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:51:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:56:13

US3342253

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:51:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:56:13

US3342253

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:51:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:56:13

US3342253

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:51:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:56:13

US3342253

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:51:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:56:13

US3342253

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:51:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:56:13

US3342253

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:51:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:56:13

US3342253

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:51:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:56:13

US3342253

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:51:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:56:13

US3342253

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:51:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:56:13

US3342253

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:51:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:56:13

US3342253

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:51:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:56:13

US3342253

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:51:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:56:13

US3342253

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:51:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:56:13

US3342253

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:51:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:56:13

US3342253

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:51:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:56:13

US3342253

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:51:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:56:13

US3342253

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:51:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:56:13

US3342253

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:51:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:56:13

US3342253

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:51:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:56:13

US3342253

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:51:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:56:13

US3342253

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:51:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:56:13

US3342253

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:51:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:56:13

US3342253

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:51:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:56:13
Data entry locked.	System	11 Sep 2020 22:20:22
User entered '18 Nov 2020 00:01'	System	11 Sep 2020 22:20:22

US3342253

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:51:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:56:13
Data entry locked.	System	11 Sep 2020 22:20:22
User entered '22 Nov 2020 23:59'	System	11 Sep 2020 22:20:22

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[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 (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-11-22T15:58:44', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '5e2b0c04-4898-4ef3-87be-f85dc2d9e6f3' User entered 'No (N)'	System	22 Nov 2020 21:58:53
	System	22 Nov 2020 21:58:53

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

Have you been exposed to someone with 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 (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-11-22T15:58:47', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '5e2b0c04-4898-4ef3-87be-f85dc2d9e6f3' User entered 'No (N)'	System	22 Nov 2020 21:58:53

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-11-22T15:58:50', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '5e2b0c04-4898-4ef3-87be-f85dc2d9e6f3' User entered '22 Nov 2020 15:58:50'	System	22 Nov 2020 21:58:53
	System	22 Nov 2020 21:58:53

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[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 (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-11-29T07:08:04', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '636b6b11-d4d5-4d67-b9e3-c42fff6dd0c8'	System	29 Nov 2020 13:08:16
User entered 'No (N)'	System	29 Nov 2020 13:08:16

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

Have you been exposed to someone with 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 (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-11-29T07:08:10', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '636b6b11-d4d5-4d67-b9e3-c42fff6dd0c8' User entered 'No (N)'	System	29 Nov 2020 13:08:16

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-11-29T07:08:14', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '636b6b11-d4d5-4d67-b9e3-c42fff6dd0c8' User entered '29 Nov 2020 07:08:14'	System	29 Nov 2020 13:08:16
	System	29 Nov 2020 13:08:16

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[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 (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-12-06T07:32:12', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '251acb65-0c96-4603-9f1c-f7cc4aec22de' User entered 'No (N)'	System	06 Dec 2020 13:32:25
	System	06 Dec 2020 13:32:25

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

Have you been exposed to someone with 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 (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-12-06T07:32:18', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '251acb65-0c96-4603-9f1c-f7cc4aec22de' User entered 'No (N)'	System	06 Dec 2020 13:32:25

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-12-06T07:32:22', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '251acb65-0c96-4603-9f1c-f7cc4aec22de' User entered '06 Dec 2020 07:32:22'	System	06 Dec 2020 13:32:25
	System	06 Dec 2020 13:32:25

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[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 (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-12-14T06:48:56', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '1f7ff05d-910e-4376-8fc3-08541b2e0bef' User entered 'No (N)'	System	14 Dec 2020 12:49:10
	System	14 Dec 2020 12:49:10

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

Have you been exposed to someone with 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 (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-12-14T06:49:03', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '1f7ff05d-910e-4376-8fc3-08541b2e0bef' User entered 'No (N)'	System	14 Dec 2020 12:49:10
	System	14 Dec 2020 12:49:10

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-12-14T06:49:06', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '1f7ff05d-910e-4376-8fc3-08541b2e0bef' User entered '14 Dec 2020 06:49:06'	System	14 Dec 2020 12:49:10
	System	14 Dec 2020 12:49:10

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[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 (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-12-21T07:30:13', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'c1ce2532-c0cc-4663-b7c8-8d8a5969b176'	System	21 Dec 2020 13:30:26
User entered 'No (N)'	System	21 Dec 2020 13:30:26

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

Have you been exposed to someone with 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 (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-12-21T07:30:19', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'c1ce2532-c0cc-4663-b7c8-8d8a5969b176'	System	21 Dec 2020 13:30:26
User entered 'No (N)'	System	21 Dec 2020 13:30:26

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-12-21T07:30:22', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'c1ce2532-c0cc-4663-b7c8-8d8a5969b176' User entered '21 Dec 2020 07:30:22'	System	21 Dec 2020 13:30:26
	System	21 Dec 2020 13:30:26

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[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 (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-12-27T15:25:40', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '28afa93f-48c8-430e-b343-500e1d3e0470' User entered 'No (N)'	System	27 Dec 2020 21:25:50
	System	27 Dec 2020 21:25:50

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

Have you been exposed to someone with 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 (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-12-27T15:25:44', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '28afa93f-48c8-430e-b343-500e1d3e0470' User entered 'No (N)'	System	27 Dec 2020 21:25:50

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2020-12-27T15:25:48', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '28afa93f-48c8-430e-b343-500e1d3e0470' User entered '27 Dec 2020 15:25:48'	System	27 Dec 2020 21:25:50
	System	27 Dec 2020 21:25:50

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[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 (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2021-01-04T05:46:07', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '3e97a356-0a54-4806-b4fa-6519c3376b70' User entered 'No (N)'	System	04 Jan 2021 11:46:26
	System	04 Jan 2021 11:46:26

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

Have you been exposed to someone with 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 (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2021-01-04T05:46:16', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '3e97a356-0a54-4806-b4fa-6519c3376b70' User entered 'No (N)'	System	04 Jan 2021 11:46:26
	System	04 Jan 2021 11:46:26

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2021-01-04T05:46:20', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '3e97a356-0a54-4806-b4fa-6519c3376b70' User entered '04 Jan 2021 05:46:20'	System	04 Jan 2021 11:46:26
	System	04 Jan 2021 11:46:26

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[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 (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2021-01-13T10:50:16', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '91a642f6-3496-4d51-9b20-e22d9315525c' User entered 'No (N)'	System	13 Jan 2021 16:50:23
	System	13 Jan 2021 16:50:23

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

Have you been exposed to someone with 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 (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2021-01-13T10:50:18', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '91a642f6-3496-4d51-9b20-e22d9315525c' User entered 'No (N)'	System	13 Jan 2021 16:50:23
	System	13 Jan 2021 16:50:23

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2021-01-13T10:50:21', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '91a642f6-3496-4d51-9b20-e22d9315525c' User entered '13 Jan 2021 10:50:21'	System	13 Jan 2021 16:50:23
	System	13 Jan 2021 16:50:23

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[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 (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2021-01-17T12:27:12', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '04457202-b8e4-4dc6-b14f-452c155aaeb6' User entered 'No (N)'	System	17 Jan 2021 18:27:20
	System	17 Jan 2021 18:27:20

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

Have you been exposed to someone with 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 (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2021-01-17T12:27:14', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '04457202-b8e4-4dc6-b14f-452c155aaeb6' User entered 'No (N)'	System	17 Jan 2021 18:27:20
	System	17 Jan 2021 18:27:20

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2021-01-17T12:27:16', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '04457202-b8e4-4dc6-b14f-452c155aaeb6' User entered '17 Jan 2021 12:27:16'	System	17 Jan 2021 18:27:20
	System	17 Jan 2021 18:27:20

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[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 (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2021-01-24T09:57:07', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '3f7f5997-504d-4005-8f5d-c5f30406d160' User entered 'No (N)'	System	24 Jan 2021 15:57:14
	System	24 Jan 2021 15:57:14

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

Have you been exposed to someone with 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 (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2021-01-24T09:57:09', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '3f7f5997-504d-4005-8f5d-c5f30406d160' User entered 'No (N)'	System	24 Jan 2021 15:57:14

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2021-01-24T09:57:12', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '3f7f5997-504d-4005-8f5d-c5f30406d160' User entered '24 Jan 2021 09:57:12'	System	24 Jan 2021 15:57:14
	System	24 Jan 2021 15:57:14

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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 (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2021-02-01T08:08:34', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '2b83f2ed-6a00-46c5-a056-4a2f6c62b16f' User entered 'No (N)'	System	01 Feb 2021 14:08:41
	System	01 Feb 2021 14:08:41

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

Have you been exposed to someone with 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 (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2021-02-01T08:08:36', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '2b83f2ed-6a00-46c5-a056-4a2f6c62b16f' User entered 'No (N)'	System	01 Feb 2021 14:08:41
	System	01 Feb 2021 14:08:41

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2021-02-01T08:08:38', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '2b83f2ed-6a00-46c5-a056-4a2f6c62b16f' User entered '01 Feb 2021 08:08:38'	System	01 Feb 2021 14:08:41
	System	01 Feb 2021 14:08:41

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[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 (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2021-02-08T07:07:22', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '47465bf1-7de4-4ec2-89ec-963b64e7e5b9' User entered 'No (N)'	System	08 Feb 2021 13:07:32
	System	08 Feb 2021 13:07:32

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

Have you been exposed to someone with 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 (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2021-02-08T07:07:24', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '47465bf1-7de4-4ec2-89ec-963b64e7e5b9' User entered 'No (N)'	System	08 Feb 2021 13:07:32
	System	08 Feb 2021 13:07:32

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2021-02-08T07:07:28', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '47465bf1-7de4-4ec2-89ec-963b64e7e5b9' User entered '08 Feb 2021 07:07:28'	System	08 Feb 2021 13:07:32
	System	08 Feb 2021 13:07:32

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[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 (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2021-02-14T06:57:19', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '14572c8c-d33b-44cd-8b4d-06ed5638b561'	System	14 Feb 2021 12:57:29
User entered 'No (N)'	System	14 Feb 2021 12:57:29

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

Have you been exposed to someone with 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 (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2021-02-14T06:57:23', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '14572c8c-d33b-44cd-8b4d-06ed5638b561'	System	14 Feb 2021 12:57:29
User entered 'No (N)'	System	14 Feb 2021 12:57:29

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2021-02-14T06:57:26', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '14572c8c-d33b-44cd-8b4d-06ed5638b561'	System	14 Feb 2021 12:57:29
User entered '14 Feb 2021 06:57:26'	System	14 Feb 2021 12:57:29

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[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 (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2021-02-21T12:53:46', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'e71171d1-c711-4956-996b-a3aeb7f48dea' User entered 'No (N)'	System	21 Feb 2021 18:53:53
	System	21 Feb 2021 18:53:53

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

Have you been exposed to someone with 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 (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2021-02-21T12:53:49', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'e71171d1-c711-4956-996b-a3aeb7f48dea' User entered 'No (N)'	System	21 Feb 2021 18:53:53
	System	21 Feb 2021 18:53:53

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2021-02-21T12:53:52', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'e71171d1-c711-4956-996b-a3aeb7f48dea' User entered '21 Feb 2021 12:53:52'	System	21 Feb 2021 18:53:53
	System	21 Feb 2021 18:53:53

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[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 (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2021-02-28T09:22:42-06:00', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'fbb0be5f-98f2-4c10-ba70-99dc0c6e634c' User entered 'No (N)'	System	28 Feb 2021 15:22:55
	System	28 Feb 2021 15:22:55

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

Have you been exposed to someone with 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 (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2021-02-28T09:22:48-06:00', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'fbb0be5f-98f2-4c10-ba70-99dc0c6e634c' User entered 'No (N)'	System	28 Feb 2021 15:22:55

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2021-02-28T09:22:50-06:00', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'fbb0be5f-98f2-4c10-ba70-99dc0c6e634c' User entered '28 Feb 2021 15:22:50'	System	28 Feb 2021 15:22:55
	System	28 Feb 2021 15:22:55

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[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 (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2021-03-07T13:07:58-06:00', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'af6e0722-1079-4e01-b879-6b3cde66906b' User entered 'No (N)'	System	07 Mar 2021 19:08:07
	System	07 Mar 2021 19:08:07

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

Have you been exposed to someone with 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 (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2021-03-07T13:08:01-06:00', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'af6e0722-1079-4e01-b879-6b3cde66906b' User entered 'No (N)'	System	07 Mar 2021 19:08:07
	System	07 Mar 2021 19:08:07

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2021-03-07T13:08:03-06:00', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'af6e0722-1079-4e01-b879-6b3cde66906b' User entered '07 Mar 2021 13:08:03'	System	07 Mar 2021 19:08:07
	System	07 Mar 2021 19:08:07

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[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 (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2021-03-14T12:51:30-05:00', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '68e05d35-4dc4-4d95-8925-3f1a3a4a761b' User entered 'No (N)'	System	14 Mar 2021 17:51:39
	System	14 Mar 2021 17:51:39

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

Have you been exposed to someone with 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 (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2021-03-14T12:51:32-05:00', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '68e05d35-4dc4-4d95-8925-3f1a3a4a761b' User entered 'No (N)'	System	14 Mar 2021 17:51:39

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2021-03-14T12:51:35-05:00', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '68e05d35-4dc4-4d95-8925-3f1a3a4a761b' User entered '14 Mar 2021 12:51:35'	System	14 Mar 2021 17:51:39

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[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 (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2021-03-21T19:35:24-05:00', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '51f02a21-d9b3-4f6b-ab7b-66b8b63f7077'	System	22 Mar 2021 00:35:32
User entered 'No (N)'	System	22 Mar 2021 00:35:32

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

Have you been exposed to someone with 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 (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2021-03-21T19:35:26-05:00', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '51f02a21-d9b3-4f6b-ab7b-66b8b63f7077'	System	22 Mar 2021 00:35:32
User entered 'No (N)'	System	22 Mar 2021 00:35:32

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2021-03-21T19:35:29-05:00', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '51f02a21-d9b3-4f6b-ab7b-66b8b63f7077'	System	22 Mar 2021 00:35:32
User entered '21 Mar 2021 19:35:29'	System	22 Mar 2021 00:35:32

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[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 (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2021-03-28T07:40:22-05:00', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'f4696ef3-59fe-4866-8fec-1bde1467f995'	System	28 Mar 2021 12:40:29
User entered 'No (N)'	System	28 Mar 2021 12:40:29

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

Have you been exposed to someone with 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 (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2021-03-28T07:40:25-05:00', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'f4696ef3-59fe-4866-8fec-1bde1467f995'	System	28 Mar 2021 12:40:29
User entered 'No (N)'	System	28 Mar 2021 12:40:29

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2021-03-28T07:40:27-05:00', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: 'f4696ef3-59fe-4866-8fec-1bde1467f995'	System	28 Mar 2021 12:40:29
User entered '28 Mar 2021 07:40:27'	System	28 Mar 2021 12:40:29

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[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 (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2021-04-04T10:31:03-05:00', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '4ba4baf1-348c-419f-9b99-5f93e16015ce' User entered 'No (N)'	System	04 Apr 2021 15:31:09
	System	04 Apr 2021 15:31:09

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

Have you been exposed to someone with 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 (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2021-04-04T10:31:05-05:00', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '4ba4baf1-348c-419f-9b99-5f93e16015ce' User entered 'No (N)'	System	04 Apr 2021 15:31:09
	System	04 Apr 2021 15:31:09

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2021-04-04T10:31:07-05:00', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '4ba4baf1-348c-419f-9b99-5f93e16015ce' User entered '04 Apr 2021 10:31:07'	System	04 Apr 2021 15:31:09
	System	04 Apr 2021 15:31:09

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[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 (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2021-04-11T19:54:46-05:00', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '1f30162b-9711-4411-abf7-d138559f0ca8'	System	12 Apr 2021 00:55:10
User entered 'Yes (Y)'	System	12 Apr 2021 00:55:10

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

Have you been exposed to someone with 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 (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2021-04-11T19:54:52-05:00', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '1f30162b-9711-4411-abf7-d138559f0ca8'	System	12 Apr 2021 00:55:10
User entered 'No (N)'	System	12 Apr 2021 00:55:10

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2021-04-11T19:54:56-05:00', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '1f30162b-9711-4411-abf7-d138559f0ca8' User entered 'No (N)'	System	12 Apr 2021 00:55:10

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2021-04-11T19:55:01-05:00', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '1f30162b-9711-4411-abf7-d138559f0ca8'	System	12 Apr 2021 00:55:10
User entered 'No (N)'	System	12 Apr 2021 00:55:10

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2021-04-11T19:55:06-05:00', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '1f30162b-9711-4411-abf7-d138559f0ca8' User entered '11 Apr 2021 19:55:06'	System	12 Apr 2021 00:55:10
	System	12 Apr 2021 00:55:10

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[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 (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2021-04-20T12:00:26-05:00', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '5ff7cdce-db25-4423-9f74-696dc900d567'	System	20 Apr 2021 17:00:43
User entered 'No (N)'	System	20 Apr 2021 17:00:43

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

Have you been exposed to someone with 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 (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2021-04-20T12:00:28-05:00', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '5ff7cdce-db25-4423-9f74-696dc900d567'	System	20 Apr 2021 17:00:43
User entered 'No (N)'	System	20 Apr 2021 17:00:43

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2021-04-20T12:00:31-05:00', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '5ff7cdce-db25-4423-9f74-696dc900d567'	System	20 Apr 2021 17:00:43
User entered '20 Apr 2021 12:00:31'	System	20 Apr 2021 17:00:43

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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 (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2021-04-26T10:48:41-05:00', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '3962edfb-798f-47c3-85d3-dd3d66636870' User entered 'No (N)'	System	26 Apr 2021 15:48:52
	System	26 Apr 2021 15:48:52

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

Have you been exposed to someone with 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 (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2021-04-26T10:48:45-05:00', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '3962edfb-798f-47c3-85d3-dd3d66636870' User entered 'No (N)'	System	26 Apr 2021 15:48:52
	System	26 Apr 2021 15:48:52

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2021-04-26T10:48:47-05:00', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '3962edfb-798f-47c3-85d3-dd3d66636870' User entered '26 Apr 2021 10:48:47'	System	26 Apr 2021 15:48:52
	System	26 Apr 2021 15:48:52

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

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 (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2021-05-02T20:44:14-05:00', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '4b4afddf-c1ee-42fc-a2d2-246f18042379'	System	03 May 2021 01:44:25
User entered 'No (N)'	System	03 May 2021 01:44:25

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

Have you been exposed to someone with 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 (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2021-05-02T20:44:17-05:00', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '4b4afddf-c1ee-42fc-a2d2-246f18042379'	System	03 May 2021 01:44:25
User entered 'No (N)'	System	03 May 2021 01:44:25

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2021-05-02T20:44:20-05:00', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '4b4afddf-c1ee-42fc-a2d2-246f18042379'	System	03 May 2021 01:44:25
User entered '02 May 2021 20:44:20'	System	03 May 2021 01:44:25

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '13 Nov 2022 00:01'	System	20 Nov 2020 07:56:13

US3342253

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:56:13
Amendment Manager: User entered '17 Nov 2022 23:59'	System	20 Nov 2020 07:56:13

US3342253

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:35:20

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 07:51:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2021-02-28T09:23:01-06:00', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '2a5786cd-bd76-4fd8-b20b-607e11062256'	System	28 Feb 2021 15:23:08
User entered 'No (N)'	System	28 Feb 2021 15:23:08

US3342253

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:35:20

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:51:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (162C072C-93FE-484C-AA8A-2A913D9D971F)', Time: '2021-02-28T09:23:06-06:00', User OID: 'PatientReportedOutcome (US3342253)', ODM File OID: '2a5786cd-bd76-4fd8-b20b-607e11062256' User entered '28 Feb 2021 15:23:06'	System	28 Feb 2021 15:23:08
	System	28 Feb 2021 15:23:08

US3342253

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:49:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Dec 2020 21:26:07

US3342253

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:49:29
User entered '7 Dec 2020'	(b) (4), (b) (6)	07 Dec 2020 21:26:07

US3342253

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:49:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	07 Dec 2020 21:26:07

US3342253

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:49:29
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 21:26:07

US3342253

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:49:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Dec 2020 21:26:12

US3342253

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:10:12
User entered 'I'	System	07 Dec 2020 21:26:12

US3342253

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:39:14
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:50:59
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	11 Jan 2021 22:02:14

US3342253

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:20

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:39:14
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:50:59
User entered '11 Jan 2021'	Ethan Shotton (b) (4) (b) (4)	11 Jan 2021 22:02:14

US3342253

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:39:14
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:50:59
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4) (b) (4)	11 Jan 2021 22:02:14

US3342253

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:39:14
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:50:59
User entered empty.	Ethan Shotton (b) (4) (b) (4)	11 Jan 2021 22:02:14

US3342253

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:39:14
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:51:39
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	11 Jan 2021 22:02:20

US3342253

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:39:14
User entered '1'	System	11 Jan 2021 22:02:20

US3342253

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:39:14
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:58:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Feb 2021 17:05:57

US3342253

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:20

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:39:14
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:58:31
User entered '08 Feb 2021'	(b) (4), (b) (6)	08 Feb 2021 17:05:57

US3342253

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:39:14
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:58:31
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	08 Feb 2021 17:05:57

US3342253

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:39:14
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:58:31
User entered empty.	(b) (4), (b) (6)	08 Feb 2021 17:05:57

US3342253

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:39:14
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:59:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Feb 2021 17:06:03

US3342253

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:39:14
User entered 'I'	System	08 Feb 2021 17:06:03

US3342253

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:39:14
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:29:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Mar 2021 16:41:58

US3342253

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:39:14
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:29:48
User entered '09 Mar 2021'	(b) (4), (b) (6)	09 Mar 2021 16:41:58

US3342253

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:39:14
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:29:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	09 Mar 2021 16:41:58

US3342253

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:39:14
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:29:48
User entered empty.	(b) (4), (b) (6)	09 Mar 2021 16:41:58

US3342253

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:39:14
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:29:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Mar 2021 16:42:03

US3342253

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:39:14
User entered 'I'	System	09 Mar 2021 16:42:03

US3342253

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:54:02
	(b) (4)	
User entered 'Yes (Y)'	Olivia Hapanowicz (b) (4)	05 Apr 2021 14:37:43
	(b) (4)	

US3342253

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:54:02
	(b) (4)	
User entered '05 Apr 2021'	Olivia Hapanowicz (b) (4)	05 Apr 2021 14:37:43
	(b) (4)	

US3342253

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:54:02
User entered 'Clinic (Clinic)'	(b) (4) Olivia Hapanowicz (b) (4) (b) (4)	05 Apr 2021 14:37:43

US3342253

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:20

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	05 Apr 2021 14:37:43

US3342253

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:54:02
	(b) (4)	
User entered 'Yes (Y)'	Olivia Hapanowicz (b) (4)	05 Apr 2021 14:38:16
	(b) (4)	

US3342253

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:54:02
	(b) (4)	
User entered '05 Apr 2021'	Olivia Hapanowicz (b) (4)	05 Apr 2021 14:38:16
	(b) (4)	

US3342253

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:54:02
	(b) (4)	
User entered '09:31'	Olivia Hapanowicz (b) (4)	05 Apr 2021 14:38:16
	(b) (4)	

US3342253

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
User entered '05 Apr 2021 09:31'	System	05 Apr 2021 14:38:16

US3342253

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:20

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:54:02
	(b) (4)	
User entered '98.0' F	Olivia Hapanowicz (b) (4)	05 Apr 2021 14:38:16
	(b) (4)	

US3342253

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:20

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:54:02
	(b) (4)	
User entered 'Oral (Oral)'	Olivia Hapanowicz (b) (4)	05 Apr 2021 14:38:16
	(b) (4)	

US3342253

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:20

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:54:02
	(b) (4)	
User entered empty.	Olivia Hapanowicz (b) (4)	05 Apr 2021 14:38:16
	(b) (4)	

US3342253

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:54:02
	(b) (4)	
User entered '80'	Olivia Hapanowicz (b) (4)	05 Apr 2021 14:38:16
	(b) (4)	

US3342253

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:20

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	05 Apr 2021 14:38:16

US3342253

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:54:02
	(b) (4)	
User entered '12'	Olivia Hapanowicz (b) (4)	05 Apr 2021 14:38:16
	(b) (4)	

US3342253

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	05 Apr 2021 14:38:16

US3342253

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:54:02
	(b) (4)	
User entered '123'	Olivia Hapanowicz (b) (4)	05 Apr 2021 14:38:16
	(b) (4)	

US3342253

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Apr 2021 14:38:16

US3342253

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:54:02
	(b) (4)	
User entered '81'	Olivia Hapanowicz (b) (4)	05 Apr 2021 14:38:16
	(b) (4)	

US3342253

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:20

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Apr 2021 14:38:16

US3342253

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:53:58
	(b) (4)	
User entered 'No (N)'	Olivia Hapanowicz (b) (4)	05 Apr 2021 14:38:21
	(b) (4)	

US3342253

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:20

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:53:58
	(b) (4)	
User entered empty.	Olivia Hapanowicz (b) (4)	05 Apr 2021 14:38:21
	(b) (4)	

US3342253

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:53:58
	(b) (4)	
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	07 Apr 2021 13:06:28
	(b) (4)	

US3342253

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:20

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:53:58
	(b) (4)	
User entered '05 Apr 2021'	Ethan Shotton (b) (4)	07 Apr 2021 13:06:28
	(b) (4)	

US3342253

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:20

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:53:58
	(b) (4)	
User entered '09:39'	Ethan Shotton (b) (4)	07 Apr 2021 13:06:28
	(b) (4)	

US3342253

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
User entered '05 Apr 2021 09:39'	System	07 Apr 2021 13:06:28

US3342253

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:53:58
	(b) (4)	
User entered 'Yes (Y)'	Olivia Hapanowicz (b) (4)	05 Apr 2021 14:38:25
	(b) (4)	

US3342253

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:20

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 14:38:25

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:29:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Mar 2021 16:44:10

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:29:59
User entered '09 Mar 2021'	(b) (4), (b) (6)	09 Mar 2021 16:44:10

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:20

[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 21:12:52
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:29:59
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	09 Mar 2021 16:44:10

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:20

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User entered 'UNBLND_DECIDE'	System	09 Mar 2021 16:44:10

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:35:20

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:30:07
User entered '09 Mar 2021'	(b) (4), (b) (6)	09 Mar 2021 16:44:25

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:35:20

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:30:07
User entered '0'	(b) (4), (b) (6)	09 Mar 2021 16:44:25

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:35:20

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:30:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Mar 2021 16:44:25

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:35:20

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:30:07
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	09 Mar 2021 16:44:25

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:35:20

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:30:07
User entered '09 Mar 2021'	(b) (4), (b) (6)	09 Mar 2021 16:44:25

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:35:20

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:30:07
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	09 Mar 2021 16:44:25

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:35:20

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:30:07
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	09 Mar 2021 16:44:25

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:35:20

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:30:07
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	09 Mar 2021 16:44:25

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:35:20

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:30:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Mar 2021 16:44:25

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:35:20

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User entered '1'	System	09 Mar 2021 16:44:25

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:35:20

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User entered 'I'	System	09 Mar 2021 16:44:25

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:35:20

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:31:40
User entered missing code ND - Not Done.	(b) (4), (b) (6)	09 Mar 2021 16:46:04

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:35:20

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:31:40
User entered missing code ND - Not Done.	(b) (4), (b) (6)	09 Mar 2021 16:46:04

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:35:20

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User entered empty.	System	09 Mar 2021 16:46:04
DataPoint set to visible.	System	09 Mar 2021 16:44:25

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:35:20

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:31:40
User entered missing code ND - Not Done.	(b) (4), (b) (6)	09 Mar 2021 16:46:04

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:35:20

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:31:40
User entered missing code ND - Not Done.	(b) (4), (b) (6)	09 Mar 2021 16:46:04

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:35:20

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User entered empty.	System	09 Mar 2021 16:46:04
DataPoint set to visible.	System	09 Mar 2021 16:44:25

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:20

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	09 Mar 2021 16:46:04

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:31:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Mar 2021 16:46:04

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:31:40
User entered '09 Mar 2021'	(b) (4), (b) (6)	09 Mar 2021 16:46:04

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:31:40
User entered '09:35'	(b) (4), (b) (6)	09 Mar 2021 16:46:04

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User entered '09 Mar 2021 09:35'	System	09 Mar 2021 16:46:04

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:31:40
User entered '98.5' F	(b) (4), (b) (6)	09 Mar 2021 16:46:04

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:31:40
User entered 'Oral (Oral)'	(b) (4), (b) (6)	09 Mar 2021 16:46:04

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:31:40
User entered empty.	(b) (4), (b) (6)	09 Mar 2021 16:46:04

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:31:40
User entered '49'	(b) (4), (b) (6)	09 Mar 2021 16:46:04

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User entered 'bpm'	System	09 Mar 2021 16:46:04

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:31:40
User entered '12'	(b) (4), (b) (6)	09 Mar 2021 16:46:04

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User entered 'breaths/min'	System	09 Mar 2021 16:46:04

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:31:40
User entered '131'	(b) (4), (b) (6)	09 Mar 2021 16:46:04

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User entered 'mmHg'	System	09 Mar 2021 16:46:04

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:31:40
User entered '80'	(b) (4), (b) (6)	09 Mar 2021 16:46:04

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:20

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User entered 'mmHg'	System	09 Mar 2021 16:46:04

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:35:20

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:31:40
User entered missing code ND - Not Done.	(b) (4), (b) (6)	09 Mar 2021 16:46:04

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:35:20

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:31:40
User entered missing code ND - Not Done.	(b) (4), (b) (6)	09 Mar 2021 16:46:04

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:35:20

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User entered empty.	System	09 Mar 2021 16:46:04
DataPoint set to visible.	System	09 Mar 2021 16:44:25

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:20

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	09 Mar 2021 16:46:04

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:31:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Mar 2021 16:46:04

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:31:40
User entered '09 Mar 2021'	(b) (4), (b) (6)	09 Mar 2021 16:46:04

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:31:40
User entered '10:35'	(b) (4), (b) (6)	09 Mar 2021 16:46:04

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User entered '09 Mar 2021 10:35'	System	09 Mar 2021 16:46:04

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:31:40
User entered '98.4' F	(b) (4), (b) (6)	09 Mar 2021 16:46:04

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:31:40
User entered 'Oral (Oral)'	(b) (4), (b) (6)	09 Mar 2021 16:46:04

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:31:40
User entered empty.	(b) (4), (b) (6)	09 Mar 2021 16:46:04

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:31:40
User entered '55'	(b) (4), (b) (6)	09 Mar 2021 16:46:04

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User entered 'bpm'	System	09 Mar 2021 16:46:04

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:31:40
User entered '12'	(b) (4), (b) (6)	09 Mar 2021 16:46:04

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User entered 'breaths/min'	System	09 Mar 2021 16:46:04

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:31:40
User entered '123'	(b) (4), (b) (6)	09 Mar 2021 16:46:04

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User entered 'mmHg'	System	09 Mar 2021 16:46:04

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:31:40
User entered '76'	(b) (4), (b) (6)	09 Mar 2021 16:46:04

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:20

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User entered 'mmHg'	System	09 Mar 2021 16:46:04

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:32:01
User entered 'No (N)'	(b) (4), (b) (6)	09 Mar 2021 16:46:55

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:20

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:32:01
User entered empty.	(b) (4), (b) (6)	09 Mar 2021 16:46:55

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:20

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:32:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Mar 2021 16:46:20

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:20

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:32:35
User entered empty.	(b) (4), (b) (6)	09 Mar 2021 16:46:20

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:20

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 21:12:52
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:32:35
User entered empty.	(b) (4), (b) (6)	09 Mar 2021 16:46:20

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:20

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User entered 'mRNA-1273'	System	09 Mar 2021 16:46:20
DataPoint set to visible.	System	09 Mar 2021 16:44:25

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:20

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:32:35
User entered '09 Mar 2021'	(b) (4), (b) (6)	09 Mar 2021 16:46:20

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:32:35
User entered '10:05'	(b) (4), (b) (6)	09 Mar 2021 16:46:20

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User entered '09 Mar 2021 10:05'	System	09 Mar 2021 16:46:20

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:32:35
User entered 'Right Arm (RIGHT ARM)'	(b) (4), (b) (6)	09 Mar 2021 16:46:20

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:32:35
User entered 'ONCE'	System	09 Mar 2021 16:46:20

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:20

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User entered 'INTRAMUSCULAR'	System	09 Mar 2021 16:46:20

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 09-Mar-2021 is recorded under Visit OL-D1 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.'	(b) (4), (b) (6)	31 Mar 2021 05:53:47
' (Site from DM).		
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
	(b) (4)	
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 09-Mar-2021 is recorded under Visit OL-D1 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.'	Olivia Hapanowicz (b) (4)	23 Mar 2021 16:15:38
	(b) (4)	
' answered with 'sample received, req number 1F636219095' (Site from DM).		
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 09-Mar-2021 is recorded under Visit OL-D1 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.'	(b) (4), (b) (6)	23 Mar 2021 06:45:01
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:33:49
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	11 Mar 2021 13:33:48
	(b) (4)	

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:20

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:33:49
User entered '09 Mar 2021'	Ethan Shotton (b) (4) (b) (4)	11 Mar 2021 13:33:48

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:20

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:33:49
User entered '09:49'	Ethan Shotton (b) (4) (b) (4)	11 Mar 2021 13:33:48

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User entered '09 Mar 2021 09:49'	System	11 Mar 2021 13:33:48

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:35:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:35:02
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	11 Mar 2021 13:34:04

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:35:20

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:35:02
User entered '09 Mar 2021'	Ethan Shotton (b) (4) (b) (4)	11 Mar 2021 13:34:04

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:35:20

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:35:02
User entered '09:51'	Ethan Shotton (b) (4) (b) (4)	11 Mar 2021 13:34:04

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User entered '09 Mar 2021 09:51'	System	11 Mar 2021 13:34:04

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:37:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Mar 2021 16:44:32

US3342253

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:12:52
User entered 'I'	System	09 Mar 2021 16:44:32

US3342253

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:24
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:36:03
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Mar 2021 14:00:30

US3342253

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:24
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:36:03
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
User entered '17 Mar 2021'	(b) (4), (b) (6)	17 Mar 2021 14:00:30

US3342253

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:24
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:36:03
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	17 Mar 2021 14:00:30

US3342253

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:24
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:36:03
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
User entered empty.	(b) (4), (b) (6)	17 Mar 2021 14:00:30

US3342253

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:24
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:36:09
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Mar 2021 14:00:37

US3342253

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:24
User entered 'I'	System	17 Mar 2021 14:00:37

US3342253

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:20

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:24
User entered '1'	System	17 Mar 2021 14:00:37
DataPoint set to visible.	System	17 Mar 2021 14:00:37

US3342253

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:53:58
	(b) (4)	
User entered 'Yes (Y)'	Olivia Hapanowicz (b) (4)	05 Apr 2021 14:41:39
	(b) (4)	

US3342253

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:53:58
	(b) (4)	
User entered '05 Apr 2021'	Olivia Hapanowicz (b) (4)	05 Apr 2021 14:41:39
	(b) (4)	

US3342253

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:53:58
User entered 'Clinic (Clinic)'	(b) (4) Olivia Hapanowicz (b) (4)	05 Apr 2021 14:41:39

US3342253

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:20

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD29'	System	05 Apr 2021 14:41:39

US3342253

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:20

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	05 Apr 2021 15:10:51

US3342253

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:53:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:10:51

US3342253

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:53:58
User entered '05 Apr 2021'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:10:51

US3342253

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:53:58
User entered '09:31'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:10:51

US3342253

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
User entered '05 Apr 2021 09:31'	System	05 Apr 2021 15:10:51

US3342253

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:20

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:53:58
User entered '98.0' F	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:10:51

US3342253

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:20

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:53:58
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:10:51

US3342253

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:20

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:53:58
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:10:51

US3342253

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:53:58
User entered '80'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:10:51

US3342253

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:20

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	05 Apr 2021 15:10:51

US3342253

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:53:58
User entered '12'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:10:51

US3342253

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	05 Apr 2021 15:10:51

US3342253

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:53:58
User entered '123'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:10:51

US3342253

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Apr 2021 15:10:51

US3342253

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:53:58
User entered '81'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:10:51

US3342253

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:20

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Apr 2021 15:10:51

US3342253

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:20

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	05 Apr 2021 15:10:51

US3342253

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:53:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:10:51

US3342253

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:53:58
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	05 Apr 2021 15:36:53
User entered '05 Apr 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 15:36:53
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Apr 2021 15:10:51
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 15:10:51

US3342253

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:53:58
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	05 Apr 2021 15:36:53
Query 'Data is required. Please provide.' answered by System data change (Site from System).		05 Apr 2021 15:36:53
User entered '10:36' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 15:36:53
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Apr 2021 15:10:51
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 15:10:51

US3342253

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
User entered '05 Apr 2021 10:36'	System	05 Apr 2021 15:36:53
User entered empty.	System	05 Apr 2021 15:10:51

US3342253

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:20

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:53:58
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	05 Apr 2021 15:36:53
Query 'Data is required. Please provide.' answered by System data change (Site from System).		05 Apr 2021 15:36:53
User entered '98.1' F reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 15:36:53
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Apr 2021 15:10:51
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 15:10:51

US3342253

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:20

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:53:58
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:10:51

US3342253

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:20

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:53:58
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:10:51

US3342253

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:53:58
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	05 Apr 2021 15:36:53
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	05 Apr 2021 15:36:53
User entered '51' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 15:36:53
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Apr 2021 15:10:51
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 15:10:51

US3342253

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:20

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	05 Apr 2021 15:36:53
User entered empty.	System	05 Apr 2021 15:10:51

US3342253

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:53:58
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	05 Apr 2021 15:36:53
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	05 Apr 2021 15:36:53
User entered '12' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 15:36:53
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Apr 2021 15:10:51
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 15:10:51

US3342253

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	05 Apr 2021 15:36:53
User entered empty.	System	05 Apr 2021 15:10:51

US3342253

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:53:58
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	05 Apr 2021 15:36:53
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	05 Apr 2021 15:36:53
User entered '115' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 15:36:53
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Apr 2021 15:10:51
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 15:10:51

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Apr 2021 15:36:53
User entered empty.	System	05 Apr 2021 15:10:51

US3342253

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:53:58
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	05 Apr 2021 15:36:53
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	05 Apr 2021 15:36:53
User entered '73' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 15:36:53
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Apr 2021 15:10:51
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 15:10:51

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:20

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Apr 2021 15:36:53
User entered empty.	System	05 Apr 2021 15:10:51

US3342253

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:53:58
	(b) (4)	
User entered 'No (N)'	Olivia Hapanowicz (b) (4)	05 Apr 2021 14:41:44
	(b) (4)	

US3342253

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:20

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:53:58
	(b) (4)	
User entered empty.	Olivia Hapanowicz (b) (4)	05 Apr 2021 14:41:44
	(b) (4)	

US3342253

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:20

[Was study treatment given?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:53:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:09:34

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:20

[If No, reason not given](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:53:58
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:09:34

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:53:58
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:09:34

US3342253

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:20

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
User entered 'mRNA-1273'	System	05 Apr 2021 15:09:34
DataPoint set to visible.	System	17 Mar 2021 14:00:37

US3342253

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:20

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:53:58
User closed query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	05 Apr 2021 15:10:07
Query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	05 Apr 2021 15:10:07
User entered '05 Apr 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 15:10:07
User opened query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	05 Apr 2021 15:09:34
User entered '04 Apr 2021'	(b) (4), (b) (6)	05 Apr 2021 15:09:34

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:53:58
User entered '10:06'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:09:34

US3342253

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
User entered '05 Apr 2021 10:06'	System	05 Apr 2021 15:10:07
User entered '04 Apr 2021 10:06'	System	05 Apr 2021 15:09:34

US3342253

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:53:58
User entered 'Right Arm (RIGHT ARM)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:09:34

US3342253

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:20

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
User entered 'ONCE'	System	05 Apr 2021 15:09:34

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:20

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	05 Apr 2021 15:09:34

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Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:53:58
	(b) (4)	
User entered 'Yes (Y)'	Olivia Hapanowicz (b) (4)	05 Apr 2021 14:41:50
	(b) (4)	

US3342253

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:20

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 14:41:50

US3342253

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:39:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:39:30

US3342253

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:39:17
User entered '13 Apr 2021'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:39:30

US3342253

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:39:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:39:30

US3342253

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:39:17
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:39:30

US3342253

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:20

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

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:39:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:39:35

US3342253

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:20

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Apr 2021 15:39:35

US3342253

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:35:20

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:47:38
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:41:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:11:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 21:25:33

US3342253

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:20

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:29:56
	(b) (4)	
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Pleural disorders, HLT: Pleural infections and inflammations, PT: Pleurisy, LLT: Pleurisy - version MedDRA\\23.0.	Coder Import (b) (4)	17 Mar 2021 08:46:40
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Mar 2021 08:46:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:39:03
Data point term sent to Coder	System	15 Mar 2021 15:41:46
Coding entries removed.	Eileen Euperio (b) (4)	15 Mar 2021 15:41:00
	(b) (4)	
Signature has been broken.	Eileen Euperio (b) (4)	15 Mar 2021 15:41:00
	(b) (4)	
User entered 'IDIOPATHIC PLEURISY WITH RECURRENCE' reason for change: Data Entry Error	Eileen Euperio (b) (4)	15 Mar 2021 15:41:00
	(b) (4)	
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:41:01
	(b) (4)	
User closed query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of PLEURISY. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 15:50:12
Query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of PLEURISY. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' answered with 'This is a recurrence of a medical condition that had resolved a year prior. Investigator believed that "recurrence" characterizes the situation better than "worsening". Please indicate if this is acceptable in EDC.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 22:49:14

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:20

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of PLEURISY. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 10:46:45
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Pleural disorders, HLT: Pleural infections and inflammations, PT: Pleurisy, LLT: Pleurisy - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 05:54:29
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 05:54:29
Data point term sent to Coder	System	13 Oct 2020 22:44:14
User entered 'Idiopathic pleurisy recurrence'	(b) (4), (b) (6)	13 Oct 2020 22:43:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:20

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:39:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:41:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 22:43:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:20

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:39:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:41:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 22:43:32

US3342253

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:20

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:39:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:41:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 22:43:32

US3342253

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:20

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:39:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:41:01
User entered '18 Sep 2020'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 22:43:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:20

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:39:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:41:01
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).	(b) (4)	13 Oct 2020 22:44:02
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Oct 2020 22:44:02
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	13 Oct 2020 22:44:02
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Oct 2020 22:43:32
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	13 Oct 2020 22:43:32
User entered 'un:un' (non-conformant).	(b) (4), (b) (6)	13 Oct 2020 22:43:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:20

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 22:44:02
User entered '18 Sep 2020 UN:UN' (non-conformant).	System	13 Oct 2020 22:43:32

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Folder: Adverse Events

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Generated On: 11 Aug 2021 22:35:20

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:39:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:41:01
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	(b) (4)	22 Oct 2020 16:20:06
User entered 'No (N)' reason for change: Data Entry Error	System	22 Oct 2020 16:20:06
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	(b) (4), (b) (6)	22 Oct 2020 16:19:43
User entered 'Yes (Y)'	System	13 Oct 2020 22:43:32

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If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:39:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:41:01
User entered '19 Oct 2020' reason for change: Data Entry Error	(b) (4)	22 Oct 2020 16:19:43
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 22:43:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:20

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 15:19:22
User entered '19 Oct 2020 :00' (non-conformant).	System	22 Oct 2020 16:20:27
User entered '19 Oct 2020 17:00'	System	22 Oct 2020 16:19:43
User entered empty.	System	13 Oct 2020 22:43:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:20

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:39:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:41:01
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 22:43:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:20

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:39:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:41:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 22:43:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:20

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:39:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:41:01
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 22:43:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:20

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:39:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:41:01
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 22:43:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:39:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:41:01
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 22:43:32

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Folder: Adverse Events

Form: Adverse Events (1)

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:39:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:41:01
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 22:43:32

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Folder: Adverse Events

Form: Adverse Events (1)

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Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:39:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:41:01
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 22:43:32

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:39:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:41:01
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 22:43:32

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Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:39:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:41:01
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 22:43:32

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Folder: Adverse Events

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:39:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:41:01
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 22:43:32

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Folder: Adverse Events

Form: Adverse Events (1)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:39:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:41:01
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 22:43:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:20

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:39:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:41:01
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 22:43:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:20

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:39:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:41:01
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	13 Oct 2020 22:44:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 22:44:31
User entered 'Related (RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Oct 2020 22:44:31
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 22:43:32
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 22:43:32

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:39:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:41:01
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	13 Oct 2020 22:44:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 22:44:31
User entered 'Related (RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Oct 2020 22:44:31
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 22:43:32
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 22:43:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:20

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:39:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:41:01
User closed query 'Per CDM: Thank you for your response. If Investigational product was withdrawn, please update Dosing Discontinuation Form. If not, please update field to indicate. Please confirm and reconcile. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:44:00
Query 'Per CDM: Thank you for your response. If Investigational product was withdrawn, please update Dosing Discontinuation Form. If not, please update field to indicate. Please confirm and reconcile. ' answered with 'Narrative not needed per CRF guidelines. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 14:33:04
User opened query 'Per CDM: Thank you for your response. If Investigational product was withdrawn, please update Dosing Discontinuation Form. If not, please update field to indicate. Please confirm and reconcile. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 20:57:02
User closed query 'Per CDM: Action taken is "Investigational Product Withdrawn" however no Dosing Discontinuation form has been added. Please review and clarify or update accordingly. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 20:57:02
Query 'Per CDM: Action taken is "Investigational Product Withdrawn" however no Dosing Discontinuation form has been added. Please review and clarify or update accordingly. ' answered with 'Dosing Discontinuation form is present in subject's chart and was registered as a discontinuation in EDC. Subject will continue in the study.' (Site from DM).	Ethan Shotton (b) (4) (b) (4)	04 Nov 2020 15:23:06
User opened query 'Per CDM: Action taken is "Investigational Product Withdrawn" however no Dosing Discontinuation form has been added. Please review and clarify or update accordingly. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 16:16:28
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 22:44:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 22:44:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:20

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Oct 2020 22:44:31
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 22:43:32
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 22:43:32

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Generated On: 11 Aug 2021 22:35:20

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:39:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:41:01
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 22:43:32

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Folder: Adverse Events

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:39:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:41:01
User entered 'I'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 22:43:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:20

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:39:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:41:01
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 22:43:32

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Folder: Adverse Events

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:39:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:41:01
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:19:43
Data Entry Error		
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	13 Oct 2020 22:43:32

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Generated On: 11 Aug 2021 22:35:20

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:39:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:41:01
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 22:43:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:20

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:39:03
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:41:01
User closed query 'Per DM CLR: SAE Narrative = ALL SCANS WERE NORMAL. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:29:50
Query 'Per DM CLR: SAE Narrative = ALL SCANS WERE NORMAL. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Narrative not needed, updated in EDC.' (Site from DM).	Olivia Hapanowicz (b) (4) (b) (4)	17 Nov 2020 16:33:23
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	13 Nov 2020 14:32:57
User opened query 'Per DM CLR: SAE Narrative = ALL SCANS WERE NORMAL. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 10:46:57
User entered 'Pt. reported a recurrence of pleurisy on 18sept2020, a week following their first vaccination. Pt. followed up with pulmonologist on 08oct2020. All scans were normal, however pt. is still experiencing symptoms.'	(b) (4), (b) (6)	13 Oct 2020 22:43:32

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Folder: Adverse Events

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Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	13 Oct 2020 22:43:32

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Folder: Adverse Events

Form: Adverse Events (1)

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Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 22:43:32

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:35:20

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:47:38
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:34:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:39:16
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Oct 2020 22:46:22
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	11 Sep 2020 22:19:57

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:20

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:57:58
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:34:40
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 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 11:21:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 11:21:41
User closed query 'Per DM CLR: this Con Med was added/ had dose increased on 08 OCT 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 17:20:15
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:41:04
Data point term sent to Coder	System	15 Mar 2021 15:40:45
Coding entries removed.	Eileen Euperio (b) (4)	15 Mar 2021 15:40:02
Query 'Per DM CLR: this Con Med was added/ had dose increased on 08 OCT 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' answered with 'this is associated with an AE, will update' (Site from DM).	Eileen Euperio (b) (4)	15 Mar 2021 15:39:35

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:20

[Name of Medication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: this Con Med was added/ had dose increased on 08 OCT 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 08:42:20
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 08:51:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	14 Oct 2020 08:51:29
Data point term sent to Coder	System	13 Oct 2020 22:48:17
User entered 'Ibuprofen'	(b) (4), (b) (6)	13 Oct 2020 22:47:24

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:20

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:57:58
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:34:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:41:04
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 22:47:24

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:57:58
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:34:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:41:04
User entered 'AE IDIOPATHIC PLEURISY WITH RECURRENCE' reason for change: Data Entry Error	Eileen Euperio (b) (4) (b) (4)	15 Mar 2021 15:40:02
User entered 'Pleurisy'	(b) (4), (b) (6)	13 Oct 2020 22:47:24

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:57:58
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:34:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:41:04
User entered '800'	(b) (4), (b) (6)	13 Oct 2020 22:47:24

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:57:58
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:34:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:41:04
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Oct 2020 22:47:24

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:57:58
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:34:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:41:04
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 22:47:24

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:20

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:57:58
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:34:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:41:04
User entered 'as needed (PRN)'	(b) (4), (b) (6)	13 Oct 2020 22:47:24

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:20

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:57:58
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:34:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:41:04
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 22:47:24

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:20

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:57:58
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:34:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:41:04
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Oct 2020 22:47:24

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:20

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:57:58
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:34:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:41:04
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 22:47:24

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:57:58
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:34:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:41:04
User entered '08 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 22:47:24

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:57:58
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:34:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:41:04
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 22:47:24

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:20

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:57:58
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:34:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:41:04
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 13:19:05
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'stop date not entered in error' (Site from DM).	John Luna (b) (4)	29 Jan 2021 19:12:42
User entered 'No (N)' reason for change: Data Entry Error	John Luna (b) (4)	29 Jan 2021 19:12:31
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 13:21:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 22:47:24

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:57:58
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:34:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:41:04
User entered '22 Oct 2020' reason for change: Data Entry Error	John Luna (b) (4)	29 Jan 2021 19:12:31
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 22:47:24

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:57:58
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:34:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:41:04
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 22:47:24

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:57:58
User entered empty.	System	13 Oct 2020 22:47:24

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:57:58
User entered empty.	System	13 Oct 2020 22:47:24

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (6), (b) (4)	23 Apr 2021 15:57:58
User entered empty.	System	13 Oct 2020 22:47:24

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:20

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE HYDROCHLORIDE, PRODUCTSYNONYM: FLEXERIL [CYCLOBENZAPRINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 11:33:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 11:33:15
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	22 Mar 2021 13:34:40
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFIXIME, PRODUCTSYNONYM: FLEXERIL [CEFIXIME] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 09:53:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 09:53:44
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:41:04
Data point term sent to Coder	System	15 Mar 2021 15:41:46
Coding entries removed.	Eileen Euperio (b) (4) (b) (4)	15 Mar 2021 15:41:19
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFIXIME, PRODUCTSYNONYM: FLEXERIL [CEFIXIME] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 21:52:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 21:52:18
Data point term sent to Coder	System	22 Oct 2020 16:09:02

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:20

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'Flexeril' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 16:08:38
Data point term sent to Coder	System	22 Oct 2020 16:08:01
User entered 'Fleril'	(b) (4), (b) (6)	22 Oct 2020 16:07:57

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:34:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:41:04
User entered 'No (N)'	(b) (4), (b) (6)	22 Oct 2020 16:07:57

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:20

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:34:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:41:04
User entered 'AE IDIOPATHIC PLEURISY WITH RECURRENCE' reason for change: Data Entry Error	Eileen Euperio (b) (4) (b) (4)	15 Mar 2021 15:41:19
User entered 'Pleurisy'	(b) (4), (b) (6)	22 Oct 2020 16:07:57

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:20

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:34:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:41:04
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 13:18:20
User entered '5' reason for change: Data Entry Error	John Luna (b) (4)	29 Jan 2021 19:11:46
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'correct, dosage id 5 mg' (Site from DM).	John Luna (b) (4)	29 Jan 2021 19:11:41
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (6), (b) (4)	14 Dec 2020 14:41:10
User entered '.5'	(b) (4), (b) (6)	22 Oct 2020 16:07:57

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:20

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:34:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:41:04
User entered 'mg (mg)'	(b) (4), (b) (6)	22 Oct 2020 16:07:57

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:20

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:34:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:41:04
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 16:07:57

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:20

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:34:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:41:04
User entered 'as needed (PRN)'	(b) (4), (b) (6)	22 Oct 2020 16:07:57

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:20

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:34:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:41:04
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 16:07:57

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:20

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:34:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:41:04
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	22 Oct 2020 16:07:57

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:34:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:41:04
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 16:07:57

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:20

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:34:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:41:04
User entered '2 Oct 2020'	(b) (4), (b) (6)	22 Oct 2020 16:07:57

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:34:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:41:04
User entered '0'	(b) (4), (b) (6)	22 Oct 2020 16:07:57

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:34:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:41:04
User entered 'No (N)'	(b) (4), (b) (6)	22 Oct 2020 16:07:57

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:34:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:41:04
User entered '19 Oct 2020'	(b) (4), (b) (6)	22 Oct 2020 16:07:57

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:34:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:41:04
User entered 'No (N)'	(b) (4), (b) (6)	22 Oct 2020 16:07:57

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 16:07:57

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 16:07:57

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 16:07:57

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:35:20

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:13:17
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:34:40
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 07:07:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 07:07:39
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 15:41:04
Data point term sent to Coder	System	15 Mar 2021 15:41:46
Coding entries removed.	Eileen Euperio (b) (4)	15 Mar 2021 15:41:32
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Oct 2020 19:25:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Oct 2020 19:25:36
Data point term sent to Coder	System	22 Oct 2020 16:11:11
User entered 'Albuterol'	(b) (4), (b) (6)	22 Oct 2020 16:10:37

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:35:20

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:13:17
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:34:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:41:04
User entered 'No (N)'	(b) (4), (b) (6)	22 Oct 2020 16:10:37

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:35:20

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:13:17
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:34:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:41:04
User entered 'AE IDIOPATHIC PLEURISY WITH RECURRENCE' reason for change: Data Entry Error	Eileen Euperio (b) (4) (b) (4)	15 Mar 2021 15:41:32
User entered 'Pleurisy'	(b) (4), (b) (6)	22 Oct 2020 16:10:37

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:35:20

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:13:17
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:34:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:41:04
User entered '1.25'	(b) (4), (b) (6)	22 Oct 2020 16:10:37

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:35:20

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:13:17
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:34:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:41:04
User entered 'mg (mg)'	(b) (4), (b) (6)	22 Oct 2020 16:10:37

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:35:20

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:13:17
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:34:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:41:04
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 16:10:37

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:35:20

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:13:17
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:34:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:41:04
User entered 'as needed (PRN)'	(b) (4), (b) (6)	22 Oct 2020 16:10:37

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:35:20

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:13:17
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:34:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:41:04
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 16:10:37

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:35:20

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:13:17
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:34:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:41:04
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4), (b) (6)	22 Oct 2020 16:10:37

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:35:20

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:13:17
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:34:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:41:04
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 16:10:37

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:35:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:13:17
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:34:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:41:04
User entered '2 Oct 2020'	(b) (4), (b) (6)	22 Oct 2020 16:10:37

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:35:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:13:17
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:34:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:41:04
User entered '0'	(b) (4), (b) (6)	22 Oct 2020 16:10:37

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:35:20

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:13:17
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:34:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:41:04
User entered 'No (N)'	(b) (4), (b) (6)	22 Oct 2020 16:10:37

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:35:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:13:17
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:34:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:41:04
User entered '19 Oct 2020'	(b) (4), (b) (6)	22 Oct 2020 16:10:37

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:35:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:13:17
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:34:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:41:04
User entered 'No (N)'	(b) (4), (b) (6)	22 Oct 2020 16:10:37

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:35:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:13:17
User entered empty.	System	22 Oct 2020 16:10:37

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:35:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:13:17
User entered empty.	System	22 Oct 2020 16:10:37

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:35:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:13:17
User entered empty.	System	22 Oct 2020 16:10:37

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:35:20

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:53:34
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:34:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:41:04
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 16:13:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 16:13:38
Data point term sent to Coder	System	22 Oct 2020 16:13:14
User entered 'Influenza vaccine'	(b) (4), (b) (6)	22 Oct 2020 16:12:35

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:35:20

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:53:34
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:34:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:41:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Oct 2020 16:12:35

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:35:20

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:53:34
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:34:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:41:04
User entered 'wellness'	(b) (4), (b) (6)	22 Oct 2020 16:12:35

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:35:20

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:53:34
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:34:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:41:04
User entered '0.5'	(b) (4), (b) (6)	22 Oct 2020 16:12:35

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:35:20

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:53:34
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:34:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:41:04
User entered 'mL (mL)'	(b) (4), (b) (6)	22 Oct 2020 16:12:35

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:35:20

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:53:34
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:34:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:41:04
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 16:12:35

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:35:20

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:53:34
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:34:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:41:04
User entered 'once (ONCE)'	(b) (4), (b) (6)	22 Oct 2020 16:12:35

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:35:20

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:53:34
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:34:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:41:04
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 16:12:35

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:35:20

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:53:34
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:34:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:41:04
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	22 Oct 2020 16:12:35

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:35:20

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:53:34
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:34:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:41:04
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 16:12:35

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:35:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:53:34
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:34:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:41:04
User entered '21 Oct 2020'	(b) (4), (b) (6)	22 Oct 2020 16:12:35

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:35:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:53:34
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:34:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:41:04
User entered '0'	(b) (4), (b) (6)	22 Oct 2020 16:12:35

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:35:20

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:53:34
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:34:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:41:04
User entered 'No (N)'	(b) (4), (b) (6)	22 Oct 2020 16:12:35

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:35:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:53:34
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:34:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:41:04
User entered '21 Oct 2020'	(b) (4), (b) (6)	22 Oct 2020 16:12:35

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:35:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:53:34
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:34:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:41:04
User entered 'No (N)'	(b) (4), (b) (6)	22 Oct 2020 16:12:35

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:35:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:53:34
User entered empty.	System	22 Oct 2020 16:12:35

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:35:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:53:34
User entered empty.	System	22 Oct 2020 16:12:35

US3342253

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:35:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:53:34
User entered empty.	System	22 Oct 2020 16:12:35

US3342253

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:35:20

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:34:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:46:27
User entered 'No (N)'	Ethan Shotton (b) (4) (b) (4)	04 Mar 2021 23:24:45

US3342253

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:35:20

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:46:32
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:45:00
User entered '13 Oct 2020'	(b) (4), (b) (6)	13 Nov 2020 14:31:33

US3342253

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:35:20

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:46:32
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:45:00
User entered 'AE (specify) (ADVERSE EVENT)'	(b) (4), (b) (6)	13 Nov 2020 14:31:33

US3342253

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:35:20

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)	27 Apr 2021 12:46:32
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:31:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 07:45:00
User closed query 'Per CDM: please record AE record number (i.e. AE #1, etc.) instead of details' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 23:11:55
Query 'Per CDM: please record AE record number (i.e. AE #1, etc.) instead of details' answered with 'UPDATED' (Site from DM).	Eileen Euperio (b) (4) (b) (4)	19 Nov 2020 23:35:48
User entered 'AE #1' reason for change: Data Entry Error	Eileen Euperio (b) (4) (b) (4)	19 Nov 2020 23:35:43
User opened query 'Per CDM: please record AE record number (i.e. AE #1, etc.) instead of details' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 14:59:22
User entered 'Idiopathic pleurisy with recurrence'	(b) (4), (b) (6)	13 Nov 2020 14:31:33