

US3342286 (Prod: Tekton Research- Austin)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:36:11

All time stamps listed in this document are displayed in GMT

US3342286

Form: Participant Creation

Data signed: (b) (4) 29 Mar 2021 16:36:06

Generated On: 11 Aug 2021 22:36:11

[Participant ID](#)

US3342286

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

US3342286

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 29 Mar 2021 16:36:13

Generated On: 11 Aug 2021 22:36:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 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 16:36:13

Generated On: 11 Aug 2021 22:36:11

Date of Birth (MMM yyyy)	(b) (6) 1983
Age	37
Age Units	YEARS
Age (Derived)	37
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 16:36:13

Generated On: 11 Aug 2021 22:36:11

Date of Informed Consent (<i>dd MMM yyyy</i>)	26 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 16:36:13

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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 16:36:13

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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 16:36:13

Generated On: 11 Aug 2021 22:36:11

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN JAN 2020
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)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 29 Mar 2021 16:36:13

Generated On: 11 Aug 2021 22:36:11

Condition	RIGHT NECK STABBING (~ 4 IN DEEP)
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2010
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	JAN 2010
Stop Year (derived)	2010

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 29 Mar 2021 16:36:13

Generated On: 11 Aug 2021 22:36:11

Condition	GENERALIZED PAIN
Start date (dd MMM yyyy)	UN UNK 2000
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)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 29 Mar 2021 16:36:13

Generated On: 11 Aug 2021 22:36:11

Condition	SURGERY FOR RIGHT NECK STABBING
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2010
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	JAN 2010
Stop Year (derived)	2010

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 29 Mar 2021 16:36:13

Generated On: 11 Aug 2021 22:36:11

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 SEP 2020
Time of assessment (00:00-23:59)	11:18 (24 HR)
Vital Signs Date and Time (derived)	26 SEP 2020 11:18
Height (xxx.x)	170.5 cm
Weight (xxx.x)	84.6 kg
BMI (xxx.x)	29.10192 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 16:36:13

Generated On: 11 Aug 2021 22:36:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 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 16:36:13

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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 16:36:13

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 23:58:31

Generated On: 11 Aug 2021 22:36:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 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 23:58:31

Generated On: 11 Aug 2021 22:36:11

What was the date of randomization? (dd MMM yyyy) 26 SEP 2020

What was the participant's randomization number? 115486

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 23:58:37

Generated On: 11 Aug 2021 22:36:11

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 23:58:37

Generated On: 11 Aug 2021 22:36:11

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)	26 SEP 2020
Time of assessment (00:00-23:59)	11:31 (24 HR)
Vital Signs Date and Time (derived)	26 SEP 2020 11:31
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)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	149 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	93 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 23:58:37

Generated On: 11 Aug 2021 22:36:11

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)	26 SEP 2020
Time of assessment (00:00-23:59)	12:51 (24 HR)
Vital Signs Date and Time (derived)	26 SEP 2020 12:51
Temperature (xxx.x)	98.6 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)	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	94 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 23:58:31

Generated On: 11 Aug 2021 22:36:11

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 23:58:31

Generated On: 11 Aug 2021 22:36:11

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) 26 SEP 2020

What was the treatment time? (00:00-23:59) 12:18 (24 HR)

Treatment Date and Time (derived) 26 SEP 2020 12:18

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 23:58:31

Generated On: 11 Aug 2021 22:36:11

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

26 SEP 2020

Collection time (00:00-23:59)

12:09 (24 HR)

Collection date and time (derived)

26 SEP 2020 12:09

US3342286

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 23:58:31

Generated On: 11 Aug 2021 22:36:11

Collection date (dd MMM yyyy)			26 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:10	26 SEP 2020 12:10
Nasopharyngeal Swab 2	No		

US3342286

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:58:31

Generated On: 11 Aug 2021 22:36:11

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 22:36:11

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 SEP 2020 12:52

PC Open Date & Time

26 SEP 2020 12:38

PC Close Date & Time

26 SEP 2020 15:08

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.5 °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	27 SEP 2020 09:09
PC Open Date & Time	26 SEP 2020 16:03
PC Close Date & Time	27 SEP 2020 11:59

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:36:11

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

98.7 °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

27 SEP 2020 15:21

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:36:11

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 ☒

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

Yes ☐

No ☒

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

PC Time Stamp 28 SEP 2020 16:31

PC Open Date & Time 28 SEP 2020 12:00

PC Close Date & Time 29 SEP 2020 11:59

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °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

29 SEP 2020 12:00

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

30 SEP 2020 22:00

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:36:11

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 ☒

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

Yes ☐

No ☒

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

PC Time Stamp 02 OCT 2020 09:41

PC Open Date & Time 01 OCT 2020 12:00

PC Close Date & Time 02 OCT 2020 11:59

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:36:11

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 ☒

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

Yes ☐

No ☒

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

PC Time Stamp 02 OCT 2020 23:59

PC Open Date & Time 02 OCT 2020 12:00

PC Close Date & Time 03 OCT 2020 11:59

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:36:11

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

26 SEP 2020 12:53

PC Open Date & Time

26 SEP 2020 12:38

PC Close Date & Time

26 SEP 2020 15:08

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:36:11

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

27 SEP 2020 09:10

PC Open Date & Time

26 SEP 2020 16:03

PC Close Date & Time

27 SEP 2020 11:59

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:36:11

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

27 SEP 2020 15:21

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:36:11

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

28 SEP 2020 16:31

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:36:11

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

29 SEP 2020 12:01

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:36:11

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

30 SEP 2020 22:01

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:36:11

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

02 OCT 2020 09:41

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:36:11

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

03 OCT 2020 00:00

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:36:11

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 ☐

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:36:11

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

No ☒

Yes ☐

PC Time stamp	26 SEP 2020 12:53
PC Open Date & Time	26 SEP 2020 12:38
PC Close Date & Time	26 SEP 2020 15:08

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:36:11

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 ☐

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:36:11

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

No ☒

Yes ☐

PC Time stamp	27 SEP 2020 09:10
PC Open Date & Time	26 SEP 2020 16:03
PC Close Date & Time	27 SEP 2020 11:59

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:36:11

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 ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:36:11

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 15:22
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:36:11

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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Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:36:11

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 16:32
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:36:11

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)

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:36:11

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 12:01
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:36:11

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

EAB) (1725)

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US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:36:11

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 22:01
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:36:11

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

53 of 1403

EAB) (1725)

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:36:11

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 09:41
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:36:11

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 00:01
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3342286

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:58:31

Generated On: 11 Aug 2021 22:36:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342286

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:58:31

Generated On: 11 Aug 2021 22:36:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342286

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:58:31

Generated On: 11 Aug 2021 22:36:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342286

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:58:31

Generated On: 11 Aug 2021 22:36:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342286

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:58:31

Generated On: 11 Aug 2021 22:36:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342286

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:58:31

Generated On: 11 Aug 2021 22:36:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342286

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 23:58:37

Generated On: 11 Aug 2021 22:36:11

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

US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 23:58:37

Generated On: 11 Aug 2021 22:36:11

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 OCT 2020
Time of assessment (00:00-23:59)	13:50 (24 HR)
Vital Signs Date and Time (derived)	26 OCT 2020 13:50
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	181 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	127 mmHg
Diastolic Blood Pressure units	MMHG

US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 23:58:37

Generated On: 11 Aug 2021 22:36:11

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

US3342286

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 23:58:37

Generated On: 11 Aug 2021 22:36:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 OCT 2020

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

US3342286

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 23:58:37

Generated On: 11 Aug 2021 22:36:11

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?

US3342286

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 23:58:37

Generated On: 11 Aug 2021 22:36:11

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	26 OCT 2020
Collection time (00:00-23:59)	14:31 (24 HR)
Collection date and time (derived)	26 OCT 2020 14:31

US3342286

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 23:58:37

Generated On: 11 Aug 2021 22:36:11

Collection date (dd MMM yyyy)			26 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:33	26 OCT 2020 14:33
Nasopharyngeal Swab 2	No		

US3342286

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:58:37

Generated On: 11 Aug 2021 22:36:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342286

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:58:31

Generated On: 11 Aug 2021 22:36:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342286

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:58:31

Generated On: 11 Aug 2021 22:36:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342286

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:58:31

Generated On: 11 Aug 2021 22:36:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342286

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:58:31

Generated On: 11 Aug 2021 22:36:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342286

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:58:31

Generated On: 11 Aug 2021 22:36:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342286

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:58:31

Generated On: 11 Aug 2021 22:36:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342286

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 23:58:37

Generated On: 11 Aug 2021 22:36:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 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

US3342286

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 23:58:37

Generated On: 11 Aug 2021 22:36:11

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	20 NOV 2020
Time of assessment (00:00-23:59)	08:46 (24 HR)
Vital Signs Date and Time (derived)	20 NOV 2020 08:46
Temperature (xxx.x)	98.6 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)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	174 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	109 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3342286

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 23:58:37

Generated On: 11 Aug 2021 22:36:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 NOV 2020

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

US3342286

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 23:58:37

Generated On: 11 Aug 2021 22:36:11

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

20 NOV 2020

Collection time (00:00-23:59)

09:08 (24 HR)

Collection date and time (derived)

20 NOV 2020 09:08

US3342286

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:58:37

Generated On: 11 Aug 2021 22:36:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	25 NOV 2020 13:53:51
Patient Cloud Open Date & Time	23 NOV 2020 00:01
Patient Cloud Close Date & Time	27 NOV 2020 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	02 DEC 2020 12:28:08
Patient Cloud Open Date & Time	30 NOV 2020 00:01
Patient Cloud Close Date & Time	04 DEC 2020 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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	07 DEC 2020 06:56:35
Patient Cloud Open Date & Time	07 DEC 2020 00:01
Patient Cloud Close Date & Time	11 DEC 2020 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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	14 DEC 2020 06:36:55
Patient Cloud Open Date & Time	14 DEC 2020 00:01
Patient Cloud Close Date & Time	18 DEC 2020 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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	21 DEC 2020 06:24:38
Patient Cloud Open Date & Time	21 DEC 2020 00:01
Patient Cloud Close Date & Time	25 DEC 2020 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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	28 DEC 2020 08:50:29
Patient Cloud Open Date & Time	28 DEC 2020 00:01
Patient Cloud Close Date & Time	01 JAN 2021 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 JAN 2021 20:24:10
Patient Cloud Open Date & Time	04 JAN 2021 00:01
Patient Cloud Close Date & Time	08 JAN 2021 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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	11 JAN 2021 14:30:17
Patient Cloud Open Date & Time	11 JAN 2021 00:01
Patient Cloud Close Date & Time	15 JAN 2021 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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 <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	18 JAN 2021 23:12:54
Patient Cloud Open Date & Time	18 JAN 2021 00:01
Patient Cloud Close Date & Time	22 JAN 2021 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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	25 JAN 2021 06:35:27
Patient Cloud Open Date & Time	25 JAN 2021 00:01
Patient Cloud Close Date & Time	29 JAN 2021 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

01 FEB 2021 00:01:34

Patient Cloud Open Date & Time

01 FEB 2021 00:01

Patient Cloud Close Date & Time

05 FEB 2021 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

08 FEB 2021 16:13:01

Patient Cloud Open Date & Time

08 FEB 2021 00:01

Patient Cloud Close Date & Time

12 FEB 2021 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 FEB 2021 08:37:52
Patient Cloud Open Date & Time	15 FEB 2021 00:01
Patient Cloud Close Date & Time	19 FEB 2021 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

22 FEB 2021 00:53:19

Patient Cloud Open Date & Time

22 FEB 2021 00:01

Patient Cloud Close Date & Time

26 FEB 2021 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAR 2021 07:12:37

Patient Cloud Open Date & Time

01 MAR 2021 00:01

Patient Cloud Close Date & Time

05 MAR 2021 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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	08 MAR 2021 06:35:28
Patient Cloud Open Date & Time	08 MAR 2021 00:01
Patient Cloud Close Date & Time	12 MAR 2021 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

15 MAR 2021 07:42:18

Patient Cloud Open Date & Time

15 MAR 2021 00:01

Patient Cloud Close Date & Time

19 MAR 2021 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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	22 MAR 2021 07:06:29
Patient Cloud Open Date & Time	22 MAR 2021 00:01
Patient Cloud Close Date & Time	26 MAR 2021 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

29 MAR 2021 20:15:06

Patient Cloud Open Date & Time

29 MAR 2021 00:01

Patient Cloud Close Date & Time

02 APR 2021 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

06 APR 2021 10:39:35

Patient Cloud Open Date & Time

05 APR 2021 00:01

Patient Cloud Close Date & Time

09 APR 2021 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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 <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	12 APR 2021 00:02:20
Patient Cloud Open Date & Time	12 APR 2021 00:01
Patient Cloud Close Date & Time	16 APR 2021 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

20 APR 2021 15:40:47

Patient Cloud Open Date & Time

19 APR 2021 00:01

Patient Cloud Close Date & Time

23 APR 2021 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 APR 2021 12:01:25

Patient Cloud Open Date & Time

26 APR 2021 00:01

Patient Cloud Close Date & Time

30 APR 2021 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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 <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"/>

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

07 MAY 2021 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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 <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"/>

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

[Patient Cloud Close Date & Time](#)

14 MAY 2021 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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 <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"/>

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

[Patient Cloud Close Date & Time](#)

21 MAY 2021 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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 <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"/>

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

[Patient Cloud Open Date & Time](#)

24 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

28 MAY 2021 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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"/>

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUN 2021 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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°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 ☐

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUN 2021 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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"/>

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

[Patient Cloud Close Date & Time](#)

18 JUN 2021 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

[Patient Cloud Close Date & Time](#)

25 JUN 2021 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUL 2021 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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"/>

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

[Patient Cloud Close Date & Time](#)

09 JUL 2021 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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"/>

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

[Patient Cloud Close Date & Time](#)

16 JUL 2021 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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"/>

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUL 2021 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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="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"/>

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

[Patient Cloud Close Date & Time](#)

30 JUL 2021 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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="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"/>

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

[Patient Cloud Close Date & Time](#)

06 AUG 2021 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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"/>

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

[Patient Cloud Close Date & Time](#)

13 AUG 2021 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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"/>

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

20 AUG 2021 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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="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"/>

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

[Patient Cloud Close Date & Time](#)

27 AUG 2021 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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"/>

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

03 SEP 2021 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

[Patient Cloud Close Date & Time](#)

10 SEP 2021 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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="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"/>

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

[Patient Cloud Close Date & Time](#)

17 SEP 2021 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

[Patient Cloud Close Date & Time](#)

24 SEP 2021 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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 <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"/>

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

[Patient Cloud Close Date & Time](#)

01 OCT 2021 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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"/>

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

[Patient Cloud Close Date & Time](#)

08 OCT 2021 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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="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"/>

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 OCT 2021 00:01
Patient Cloud Close Date & Time	15 OCT 2021 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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"/>

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

Patient Cloud Open Date & Time	25 OCT 2021 00:01
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Patient Cloud Close Date & Time	29 OCT 2021 23:59
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US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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="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"/>

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

05 NOV 2021 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

12 NOV 2021 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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"/>

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

[Patient Cloud Close Date & Time](#)

19 NOV 2021 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

26 NOV 2021 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

[Patient Cloud Close Date & Time](#)

03 DEC 2021 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

[Patient Cloud Close Date & Time](#)

10 DEC 2021 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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 <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"/>

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 DEC 2021 00:01
Patient Cloud Close Date & Time	17 DEC 2021 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 DEC 2021 00:01
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Patient Cloud Close Date & Time	24 DEC 2021 23:59
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US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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="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"/>

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

31 DEC 2021 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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="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"/>

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JAN 2022 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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"/>

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

[Patient Cloud Close Date & Time](#)

14 JAN 2022 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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 <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"/>

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

[Patient Cloud Close Date & Time](#)

21 JAN 2022 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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"/>

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

[Patient Cloud Open Date & Time](#)

24 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JAN 2022 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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="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"/>

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

[Patient Cloud Close Date & Time](#)

04 FEB 2022 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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"/>

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

11 FEB 2022 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

[Patient Cloud Close Date & Time](#)

18 FEB 2022 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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"/>

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

[Patient Cloud Close Date & Time](#)

25 FEB 2022 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

DAY 523

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

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

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

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

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

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

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

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

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAR 2022 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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"/>

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

[Patient Cloud Close Date & Time](#)

11 MAR 2022 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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 ☐

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

[Patient Cloud Close Date & Time](#)

18 MAR 2022 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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 <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"/>

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

[Patient Cloud Close Date & Time](#)

25 MAR 2022 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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 ☐

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

[Patient Cloud Open Date & Time](#)

28 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 APR 2022 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

[Patient Cloud Close Date & Time](#)

08 APR 2022 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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 ☐

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 APR 2022 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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 ☐

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

[Patient Cloud Close Date & Time](#)

22 APR 2022 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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 ☐

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 APR 2022 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

DAY 586

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

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

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

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

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

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

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

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

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAY 2022 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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 ☐

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2022 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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="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"/>

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

[Patient Cloud Close Date & Time](#)

20 MAY 2022 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2022 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2022 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2022 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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="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"/>

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

[Patient Cloud Close Date & Time](#)

17 JUN 2022 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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"/>

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2022 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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"/>

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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"/>

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

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

Date and time of submission

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04 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2022 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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"/>

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

[Patient Cloud Close Date & Time](#)

15 JUL 2022 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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 <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"/>

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2022 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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 <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"/>

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2022 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

DAY 677

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

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

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

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

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

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

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

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

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2022 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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="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"/>

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2022 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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"/>

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

[Patient Cloud Close Date & Time](#)

19 AUG 2022 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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 <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"/>

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

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26 AUG 2022 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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 <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"/>

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2022 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

[Patient Cloud Close Date & Time](#)

09 SEP 2022 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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"/>

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

[Patient Cloud Close Date & Time](#)

16 SEP 2022 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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"/>

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

[Patient Cloud Close Date & Time](#)

23 SEP 2022 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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"/>

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

[Patient Cloud Close Date & Time](#)

30 SEP 2022 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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"/>

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

[Patient Cloud Close Date & Time](#)

07 OCT 2022 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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"/>

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

[Patient Cloud Close Date & Time](#)

14 OCT 2022 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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"/>

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

[Patient Cloud Close Date & Time](#)

21 OCT 2022 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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"/>

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2022 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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="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"/>

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2022 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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 <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"/>

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

[Patient Cloud Close Date & Time](#)

11 NOV 2022 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

[Patient Cloud Close Date & Time](#)

18 NOV 2022 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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="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"/>

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2022 23:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

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

28 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2022 23:59

US3342286

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:36:11

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		01 MAR 2021 07:12:51

US3342286

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 16:36:13

Generated On: 11 Aug 2021 22:36:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342286

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 16:36:13

Generated On: 11 Aug 2021 22:36:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342286

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 16:36:06

Generated On: 11 Aug 2021 22:36:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342286

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 16:36:06

Generated On: 11 Aug 2021 22:36:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342286

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 16:36:13

Generated On: 11 Aug 2021 22:36:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342286

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 16:36:13

Generated On: 11 Aug 2021 22:36:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342286

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 29 Mar 2021 16:36:13

Generated On: 11 Aug 2021 22:36:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342286

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 29 Mar 2021 16:36:13

Generated On: 11 Aug 2021 22:36:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342286

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:36:11

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 _____

US3342286

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

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)	

US3342286

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:36:11

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.

US3342286

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:36:11

Was the sample collected?

Yes ☐

No ☐

Collection date (*dd MMM yyyy*)

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

Collection date and time (derived)

US3342286

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:11

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3342286

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:36:11

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"/>

US3342286

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:36:11

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3342286

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

Form: Unblinding

Data signed: (b) (4) 12 Apr 2021 15:55:35

Generated On: 11 Aug 2021 22:36:11

Date of updated informed consent (*dd MMM yyyy*) 25 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (*dd MMM yyyy*) 25 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☐ Placebo ☐ Not Administered ☒

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3342286

Folder: Unscheduled 19 Mar 2021

Form: Unscheduled Visit Assessment

Data signed: (b) (4) 29 Mar 2021 16:36:13

Generated On: 11 Aug 2021 22:36:11

Visit Date	19 MAR 2021
Please check all assessments that apply for this visit	
Physical Exam	True
Vital Signs	True
Immunogenicity Assessment	False
Pregnancy Test	False

US3342286

Folder: Unscheduled 19 Mar 2021

Form: Vital Signs

Data signed: (b) (4) 29 Mar 2021 16:36:13

Generated On: 11 Aug 2021 22:36:11

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	19 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	10:07 (24 HR)
Vital Signs Date and Time (derived)	19 MAR 2021 10:07
Temperature (<i>xxx.x</i>)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	71 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	181 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	117 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3342286

Folder: Unscheduled 19 Mar 2021

Form: Physical Examination

Data signed: (b) (4) 29 Mar 2021 16:36:13

Generated On: 11 Aug 2021 22:36:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 MAR 2021

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

US3342286

Folder: Unscheduled 21 Oct 2020

Form: Unscheduled Visit Assessment

Data signed: (b) (4) 29 Mar 2021 16:36:13

Generated On: 11 Aug 2021 22:36:11

Visit Date	21 OCT 2020
Please check all assessments that apply for this visit	
Physical Exam	True
Vital Signs	True
Immunogenicity Assessment	False
Pregnancy Test	False

US3342286

Folder: Unscheduled 21 Oct 2020

Form: Vital Signs

Data signed: (b) (4) 29 Mar 2021 16:36:13

Generated On: 11 Aug 2021 22:36:11

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 OCT 2020
Time of assessment (00:00-23:59)	13:27 (24 HR)
Vital Signs Date and Time (derived)	21 OCT 2020 13:27
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	165 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	109 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3342286

Folder: Unscheduled 21 Oct 2020

Form: Physical Examination

Data signed: (b) (4) 29 Mar 2021 16:36:13

Generated On: 11 Aug 2021 22:36:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 OCT 2020

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

US3342286

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Mar 2021 23:42:33

Generated On: 11 Aug 2021 22:36:11

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Mar 2021 23:42:33

Generated On: 11 Aug 2021 22:36:11

AEID	
Adverse event	HYPERTENSION (UNSPECIFIED)
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	21 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input 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"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Mar 2021 23:42:33

Generated On: 11 Aug 2021 22:36:11

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

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Mar 2021 23:42:33

Generated On: 11 Aug 2021 22:36:11

 CALLED PT TO F/U ON
 ELEVATED BP. PT DID NOT
 ANSWER, BUT PI LEFT
 DETAILED VOICEMAIL.
 REMINDED PT OF VISIT AND
RECOMMENDATION HE SEE A
 PCP RE: BP. THIS
 RECOMMENDATION WAS
REITERATED BY DR. PICKRELL
 AT A SUBSEQUENT VISIT. PI
 OFFERED THAT WE HAVE A
 LIST OF ACCESSIBLE CLINICS
IN CASE PT IN UNABLE TO SEE
HIS WIFE'S MD AS HE HOPED. PI
 SPECIFICALLY MENTIONED
LONE STAR CIRCLE OF CARE,
 WHICH HAS LOCATIONS IN
TRAVIS AND WILLIAMSON
COUNTIES. LIST OBTAINED
FROM CITY OF AUSTIN
WEBSITE, WHICH PI
REFERENCED TO HIM. (b) (6)
 (b) (6) 02NOV2020.

UPDATE: AT PT VISIT 3
(20NOV20230) PT WAS ASKED IF
HE F/U WITH PCP/MEDICAL
PROVIDER REGARDING
ELEVATED BP. PT STATED
THAT HE HAD NOT FOLLOWED
UP WITH ANYONE IRT THE
ELEVATED BP. PT STILL
INTENDS ON SEEING MEDICAL
PROVIDER (SPECIFICALLY
STATING "LONE STAR") AFTER

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Mar 2021 23:42:33

Generated On: 11 Aug 2021 22:36:11

THANKSGIVING. HE WAS
INFORMED THAT HE WOULD
BE ABLE TO HAVE AN
APPOINTMENT AT THAT TIME.
PT NEEDS TO CALL CLINIC IN
ORDER TO SCHEDULED
APPOINTMENT AFTER
THANKSGIVING. WILL F/U
WITH PT AND MONITOR FOR
ADDITIONAL INFORMATION.
DUE TO PATIENT'S ELEVATED
BP AT VISIT 3, SX DIRECTED
PHYSICAL CONDUCTED
FOCUSED ON
CARDIOVASCULAR
ASSESSMENT. DAO 20NOV2020.

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

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 22 Mar 2021 13:36:17

Generated On: 11 Aug 2021 22:36:11

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

Yes ☒

No ☐

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

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Mar 2021 13:36:16

Generated On: 11 Aug 2021 22:36:11

Name of Medication DIPHENHYDRAMINE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 50

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 ☐

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US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Mar 2021 13:36:16

Generated On: 11 Aug 2021 22:36:11

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

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Mar 2021 13:36:16

Generated On: 11 Aug 2021 22:36:11

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication GENERALIZED PAIN

Dose per administration 200

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 ☐

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US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Mar 2021 13:36:16

Generated On: 11 Aug 2021 22:36:11

	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)	UN UNK 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Mar 2021 13:36:16

Generated On: 11 Aug 2021 22:36:11

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION UNSPECIFIED

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Mar 2021 13:36:16

Generated On: 11 Aug 2021 22:36:11

	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)	25 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3342286

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 22 Mar 2021 13:36:17

Generated On: 11 Aug 2021 22:36:11

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3342286

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 29 Mar 2021 16:36:06

Generated On: 11 Aug 2021 22:36:11

Date of dosing discontinuation (dd MMM yyyy)	21 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

US3342286

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:36:11

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

US3342286 (Prod: Tekton Research- Austin)

US3342286

Form: Participant Creation

Generated On: 11 Aug 2021 22:36:11

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:17:00
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:06
User entered 'US3342286'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Sep 2020 16:26:03

US3342286

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:36:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered 'Yes (Y)'	Darrell O'Brien (b) (4)	26 Sep 2020 16:59:13

US3342286

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered '26 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Sep 2020 16:26:05

US3342286

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:36:11

[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 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered 'Clinic (Clinic)'	Darrell O'Brien (b) (4)	26 Sep 2020 16:59:13

US3342286

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:36:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User entered 'SCRN'	System	26 Sep 2020 16:59:13

US3342286

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:36:11

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered (b) (6) 1983'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Sep 2020 16:26:06

US3342286

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:36:11

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered '37'	Darrell O'Brien (b) (4)	26 Sep 2020 16:59:24

US3342286

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:36:11

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User entered 'YEARS'	System	26 Sep 2020 16:59:24

US3342286

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:36:11

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User entered '37'	System	26 Sep 2020 16:59:39

US3342286

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:36:11

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered 'Male (M)'	Darrell O'Brien (b) (4)	26 Sep 2020 16:59:24

US3342286

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:36:11

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Darrell O'Brien (b) (4)	26 Sep 2020 16:59:24

US3342286

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:36:11

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered 'I'	Darrell O'Brien (b) (4)	26 Sep 2020 16:59:24

US3342286

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:36:11

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered '0'	Darrell O'Brien (b) (4)	26 Sep 2020 16:59:24

US3342286

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:36:11

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered '0'	Darrell O'Brien (b) (4)	26 Sep 2020 16:59:24

US3342286

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:36:11

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered '0'	Darrell O'Brien (b) (4)	26 Sep 2020 16:59:24

US3342286

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:36:11

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered '0'	Darrell O'Brien (b) (4)	26 Sep 2020 16:59:24

US3342286

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:36:11

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered '0'	Darrell O'Brien (b) (4)	26 Sep 2020 16:59:24

US3342286

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:36:11

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered empty.	Darrell O'Brien (b) (4)	26 Sep 2020 16:59:24

US3342286

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:36:11

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered '0'	Darrell O'Brien (b) (4)	26 Sep 2020 16:59:24

US3342286

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:36:11

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered '0'	Darrell O'Brien (b) (4)	26 Sep 2020 16:59:24

US3342286

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:36:11

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered '26 Sep 2020'	Darrell O'Brien (b) (4)	26 Sep 2020 16:59:39

US3342286

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User entered 'Sep 2020'	System	26 Sep 2020 16:59:39

US3342286

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User entered '2020'	System	26 Sep 2020 16:59:39

US3342286

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:36:11

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered 'Amendment 3 (3)'	Darrell O'Brien (b) (4)	26 Sep 2020 16:59:39

US3342286

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered 'Yes (Y)'	Darrell O'Brien (b) (4)	26 Sep 2020 16:59:39

US3342286

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:36:11

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered empty.	Darrell O'Brien (b) (4)	26 Sep 2020 16:59:39

US3342286

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:36:11

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered empty.	Darrell O'Brien (b) (4)	26 Sep 2020 16:59:39

US3342286

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:36:11

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered 'No (N)'	Darrell O'Brien (b) (4)	26 Sep 2020 16:59:39

US3342286

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:36:11

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Sep 2020 16:26:05

US3342286

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:36:11

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User entered 'I'	System	26 Sep 2020 16:59:44

US3342286

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered 'Yes (Y)'	Darrell O'Brien (b) (4)	26 Sep 2020 16:59:44

US3342286

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:36:11

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered 'Yes (Y)'	Darrell O'Brien (b) (4)	26 Sep 2020 17:02:17

US3342286

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:36:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	26 Sep 2020 17:03:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Sep 2020 17:03:44
Data point term sent to Coder	System	26 Sep 2020 17:03:00
User entered 'Seasonal Allergies'	Darrell O'Brien (b) (4)	26 Sep 2020 17:02:42

US3342286

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered 'un Jan 2020'	Darrell O'Brien (b) (4)	26 Sep 2020 17:02:42

US3342286

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:36:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered '0'	Darrell O'Brien (b) (4)	26 Sep 2020 17:02:42

US3342286

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:36:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	(b) (4) System	26 Sep 2020 17:02:54
User entered 'Yes (Y)' reason for change: Data Entry Error	Darrell O'Brien (b) (4) (b) (4)	26 Sep 2020 17:02:54
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	26 Sep 2020 17:02:42
User entered 'No (N)'	Darrell O'Brien (b) (4) (b) (4)	26 Sep 2020 17:02:42

US3342286

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered empty.	Darrell O'Brien (b) (4)	26 Sep 2020 17:02:42

US3342286

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:36:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered '0'	Darrell O'Brien (b) (4)	26 Sep 2020 17:02:42

US3342286

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User entered 'Jan 2020'	System	26 Sep 2020 17:02:42

US3342286

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User entered '2020'	System	26 Sep 2020 17:02:42

US3342286

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User entered empty.	System	26 Sep 2020 17:02:42

US3342286

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User entered empty.	System	26 Sep 2020 17:02:42

US3342286

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:36:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Stab wound, LLT: Stab wound - version MedDRA\\23.0.	Coder Import (b) (4)	27 Sep 2020 04:36:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	27 Sep 2020 04:36:37
Data point term sent to Coder	System	26 Sep 2020 17:04:02
User entered 'Right Neck Stabbing (~ 4 in deep)'	Darrell O'Brien (b) (4)	26 Sep 2020 17:03:40

US3342286

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered 'un UNK 2010'	Darrell O'Brien (b) (4)	26 Sep 2020 17:03:40

US3342286

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:36:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered '0'	Darrell O'Brien (b) (4)	26 Sep 2020 17:03:40

US3342286

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:36:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered 'No (N)'	Darrell O'Brien (b) (4)	26 Sep 2020 17:03:40

US3342286

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered 'un UNK 2010'	Darrell O'Brien (b) (4)	26 Sep 2020 17:03:40

US3342286

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:36:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered '0'	Darrell O'Brien (b) (4)	26 Sep 2020 17:03:40

US3342286

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User entered 'Jan 2010'	System	26 Sep 2020 17:03:40

US3342286

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User entered '2010'	System	26 Sep 2020 17:03:40

US3342286

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User entered 'Jan 2010'	System	26 Sep 2020 17:03:40

US3342286

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User entered '2010'	System	26 Sep 2020 17:03:40

US3342286

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:36:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Pain, LLT: General body pain - version MedDRA\\23.0.	Coder Import (b) (4)	26 Sep 2020 17:04:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Sep 2020 17:04:45
Data point term sent to Coder	System	26 Sep 2020 17:04:02
User entered 'Generalized Pain'	Darrell O'Brien (b) (4)	26 Sep 2020 17:03:09

US3342286

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered 'un UNK 2000'	Darrell O'Brien (b) (4)	26 Sep 2020 17:03:09

US3342286

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:36:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered '0'	Darrell O'Brien (b) (4)	26 Sep 2020 17:03:09

US3342286

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:36:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered 'Yes (Y)'	Darrell O'Brien (b) (4)	26 Sep 2020 17:03:09

US3342286

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered empty.	Darrell O'Brien (b) (4)	26 Sep 2020 17:03:09

US3342286

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:36:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered '0'	Darrell O'Brien (b) (4)	26 Sep 2020 17:03:09

US3342286

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User entered 'Jan 2000'	System	26 Sep 2020 17:03:09

US3342286

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User entered '2000'	System	26 Sep 2020 17:03:09

US3342286

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User entered empty.	System	26 Sep 2020 17:03:09

US3342286

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User entered empty.	System	26 Sep 2020 17:03:09

US3342286

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:36:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Head, neck and oral cavity therapeutic procedures NEC, PT: Neck surgery, LLT: Neck surgery - version MedDRA\23.0.	Coder Import (b) (4)	14 Oct 2020 08:46:29
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	14 Oct 2020 08:46:29
Data point term sent to Coder	System	26 Sep 2020 17:05:03
User entered 'Surgery for Right Neck Stabbing'	Darrell O'Brien (b) (4)	26 Sep 2020 17:04:12

US3342286

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered 'un UNK 2010'	Darrell O'Brien (b) (4)	26 Sep 2020 17:04:12

US3342286

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:36:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered '0'	Darrell O'Brien (b) (4)	26 Sep 2020 17:04:12

US3342286

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:36:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered 'No (N)'	Darrell O'Brien (b) (4)	26 Sep 2020 17:04:12

US3342286

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered 'un UNK 2010'	Darrell O'Brien (b) (4)	26 Sep 2020 17:04:12

US3342286

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:36:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered '0'	Darrell O'Brien (b) (4)	26 Sep 2020 17:04:12

US3342286

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User entered 'Jan 2010'	System	26 Sep 2020 17:04:12

US3342286

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User entered '2010'	System	26 Sep 2020 17:04:12

US3342286

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User entered 'Jan 2010'	System	26 Sep 2020 17:04:12

US3342286

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User entered '2010'	System	26 Sep 2020 17:04:12

US3342286

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered 'Yes (Y)'	Darrell O'Brien (b) (4)	26 Sep 2020 17:02:12

US3342286

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered '26 Sep 2020'	Darrell O'Brien (b) (4)	26 Sep 2020 17:02:12

US3342286

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered '11:18'	Darrell O'Brien (b) (4)	26 Sep 2020 17:02:12

US3342286

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User entered '26 Sep 2020 11:18'	System	26 Sep 2020 17:02:12

US3342286

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered '170.5' cm	(b) (4) Darrell O'Brien (b) (4)	26 Sep 2020 17:02:12
DataPoint set to visible.	(b) (4) System	26 Sep 2020 16:59:44

US3342286

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered '84.6' kg	(b) (4) Darrell O'Brien (b) (4)	26 Sep 2020 17:02:12
DataPoint set to visible.	(b) (4) System	26 Sep 2020 16:59:44

US3342286

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User entered '29.10192'	System	26 Sep 2020 17:02:12
DataPoint set to visible.	System	26 Sep 2020 16:59:44

US3342286

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User entered 'kg/m2'	System	26 Sep 2020 17:02:12
DataPoint set to visible.	System	26 Sep 2020 16:59:44

US3342286

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered missing code ND - Not Done.	Darrell O'Brien (b) (4)	26 Sep 2020 17:02:12

US3342286

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered empty.	Darrell O'Brien (b) (4)	26 Sep 2020 17:02:12

US3342286

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered empty.	Darrell O'Brien (b) (4)	26 Sep 2020 17:02:12

US3342286

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered missing code ND - Not Done.	Darrell O'Brien (b) (4)	26 Sep 2020 17:02:12

US3342286

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User entered 'bpm'	System	26 Sep 2020 17:02:12

US3342286

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered missing code ND - Not Done.	Darrell O'Brien (b) (4)	26 Sep 2020 17:02:12

US3342286

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User entered 'breaths/min'	System	26 Sep 2020 17:02:12

US3342286

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered missing code ND - Not Done.	Darrell O'Brien (b) (4)	26 Sep 2020 17:02:12

US3342286

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User entered 'mmHg'	System	26 Sep 2020 17:02:12

US3342286

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered missing code ND - Not Done.	Darrell O'Brien (b) (4)	26 Sep 2020 17:02:12

US3342286

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User entered 'mmHg'	System	26 Sep 2020 17:02:12

US3342286

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59

US3342286

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59

US3342286

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:36:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered 'Yes (Y)'	Darrell O'Brien (b) (4)	26 Sep 2020 17:01:05

US3342286

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:36:11

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered '26 Sep 2020'	Darrell O'Brien (b) (4)	26 Sep 2020 17:01:05

US3342286

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:36:11

[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 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered 'No (N)'	Darrell O'Brien (b) (4)	26 Sep 2020 17:01:29

US3342286

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:36:11

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 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered 'No (N)'	Darrell O'Brien (b) (4)	26 Sep 2020 17:01:29

US3342286

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:36:11

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 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered 'Yes (Y)'	Darrell O'Brien (b) (4)	26 Sep 2020 17:01:29

US3342286

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:36:11

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 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered 'No (N)'	Darrell O'Brien (b) (4)	26 Sep 2020 17:01:29

US3342286

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:36:11

[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 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered 'No (N)'	Darrell O'Brien (b) (4)	26 Sep 2020 17:01:29

US3342286

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:36:11

[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 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered 'No (N)'	Darrell O'Brien (b) (4)	26 Sep 2020 17:01:29

US3342286

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:36:11

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 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered 'No (N)'	Darrell O'Brien (b) (4)	26 Sep 2020 17:01:29

US3342286

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:36:11

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 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered 'No (N)'	Darrell O'Brien (b) (4)	26 Sep 2020 17:01:29

US3342286

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:36:11

[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 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered 'No (N)'	Darrell O'Brien (b) (4)	26 Sep 2020 17:01:29

US3342286

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:36:11

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 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered 'No (N)'	Darrell O'Brien (b) (4)	26 Sep 2020 17:01:29

US3342286

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:36:11

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 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered 'No (N)'	Darrell O'Brien (b) (4)	26 Sep 2020 17:01:29

US3342286

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:36:11

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered 'No (N)'	Darrell O'Brien (b) (4)	26 Sep 2020 17:01:29

US3342286

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:36:11

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered empty.	Darrell O'Brien (b) (4)	26 Sep 2020 17:01:29

US3342286

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:36:11

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered '0'	Darrell O'Brien (b) (4)	26 Sep 2020 17:01:29

US3342286

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered '0'	Darrell O'Brien (b) (4)	26 Sep 2020 17:01:29

US3342286

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:36:11

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 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered '0'	Darrell O'Brien (b) (4)	26 Sep 2020 17:01:29

US3342286

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:36:11

[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 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered '0'	Darrell O'Brien (b) (4)	26 Sep 2020 17:01:29

US3342286

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:36:11

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 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered '0'	Darrell O'Brien (b) (4)	26 Sep 2020 17:01:29

US3342286

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered 'I'	Darrell O'Brien (b) (4)	26 Sep 2020 17:01:29

US3342286

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:36:11

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered '0'	Darrell O'Brien (b) (4)	26 Sep 2020 17:01:29

US3342286

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:36:11

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:38:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered empty.	Darrell O'Brien (b) (4)	26 Sep 2020 17:01:29

US3342286

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:36:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:32
User entered 'Yes (Y)'	Darrell O'Brien (b) (4)	26 Sep 2020 17:06:05

US3342286

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:32
User entered '26 Sep 2020'	Darrell O'Brien (b) (4)	26 Sep 2020 17:06:05

US3342286

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:36:11

[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 16:13:15
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:32
User entered 'Clinic (Clinic)'	Darrell O'Brien (b) (4)	26 Sep 2020 17:06:05

US3342286

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:36:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User entered 'VISIT1'	System	26 Sep 2020 17:06:05

US3342286

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:32
User entered '26 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Sep 2020 16:57:38

US3342286

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:32
User entered '115486'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Sep 2020 16:57:38

US3342286

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:32
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Sep 2020 16:57:38

US3342286

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:36:11

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 16:13:15
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:32
User entered 'No (N)'	Darrell O'Brien (b) (4)	26 Sep 2020 17:00:53

US3342286

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:36:11

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 16:13:15
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:32
User entered 'No (N)'	Darrell O'Brien (b) (4)	26 Sep 2020 17:00:53

US3342286

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:32
User entered 'No (N)'	Darrell O'Brien (b) (4)	26 Sep 2020 17:00:53

US3342286

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:36:11

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:32
User entered 'No (N)'	Darrell O'Brien (b) (4)	26 Sep 2020 17:00:53

US3342286

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:36:11

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:32
User entered 'No (N)'	Darrell O'Brien (b) (4)	26 Sep 2020 17:00:53

US3342286

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:32
User entered 'No (N)'	(b) (4) Darrell O'Brien (b) (4)	26 Sep 2020 17:00:53
DataPoint set to visible.	(b) (4) System	26 Sep 2020 16:59:39

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:36:11

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered missing code ND - Not Done.	(b) (4) Eileen Euperio (b) (4)	26 Sep 2020 18:05:17

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:36:11

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered missing code ND - Not Done.	(b) (4) Eileen Euperio (b) (4)	26 Sep 2020 18:05:17

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:36:11

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered missing code ND - Not Done.	Eileen Euperio (b) (4)	26 Sep 2020 18:05:17

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:36:11

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered missing code ND - Not Done.	Eileen Euperio (b) (4)	26 Sep 2020 18:05:17

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User accepted default value 'Pre-Dose (PREDOSE)'	Eileen Euperio (b) (4)	26 Sep 2020 18:05:17
	(b) (4)	

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered 'Yes (Y)'	Eileen Euperio (b) (4)	26 Sep 2020 18:05:17

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered '26 Sep 2020'	Eileen Euperio (b) (4)	26 Sep 2020 18:05:17

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered '11:31'	Eileen Euperio (b) (4)	26 Sep 2020 18:05:17

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User entered '26 Sep 2020 11:31'	System	26 Sep 2020 18:05:17

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered '98.0' F	Eileen Euperio (b) (4)	26 Sep 2020 18:05:17

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered 'Oral (Oral)'	Eileen Euperio (b) (4)	26 Sep 2020 18:05:17

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered empty.	(b) (4) Eileen Euperio (b) (4)	26 Sep 2020 18:05:17

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered '86'	Eileen Euperio (b) (4)	26 Sep 2020 18:05:17

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User entered 'bpm'	System	26 Sep 2020 18:05:17

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered '14'	Eileen Euperio (b) (4)	26 Sep 2020 18:05:17

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User entered 'breaths/min'	System	26 Sep 2020 18:05:17

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered '149'	Eileen Euperio (b) (4)	26 Sep 2020 18:05:17

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User entered 'mmHg'	System	26 Sep 2020 18:05:17

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered '93'	Eileen Euperio (b) (4)	26 Sep 2020 18:05:17

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User entered 'mmHg'	System	26 Sep 2020 18:05:17

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:36:11

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered missing code ND - Not Done.	Eileen Euperio (b) (4)	26 Sep 2020 18:05:17

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:36:11

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered missing code ND - Not Done.	Eileen Euperio (b) (4)	26 Sep 2020 18:05:17

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User accepted default value 'Post-Dose (POSTDOSE)'	Eileen Euperio (b) (4) (b) (4)	26 Sep 2020 18:05:17

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered 'Yes (Y)'	(b) (4) Eileen Euperio (b) (4)	26 Sep 2020 18:05:17

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered '26 Sep 2020'	Eileen Euperio (b) (4)	26 Sep 2020 18:05:17

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered '12:51'	Eileen Euperio (b) (4)	26 Sep 2020 18:05:17

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User entered '26 Sep 2020 12:51'	System	26 Sep 2020 18:05:17

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered '98.6' F	Eileen Euperio (b) (4)	26 Sep 2020 18:05:17

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered 'Oral (Oral)'	Eileen Euperio (b) (4)	26 Sep 2020 18:05:17

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered empty.	(b) (4) Eileen Euperio (b) (4)	26 Sep 2020 18:05:17

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered '80'	Eileen Euperio (b) (4)	26 Sep 2020 18:05:17

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User entered 'bpm'	System	26 Sep 2020 18:05:17

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered '12'	Eileen Euperio (b) (4)	26 Sep 2020 18:05:17

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User entered 'breaths/min'	System	26 Sep 2020 18:05:17

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered '146'	Eileen Euperio (b) (4)	26 Sep 2020 18:05:17

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User entered 'mmHg'	System	26 Sep 2020 18:05:17

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered '94'	Eileen Euperio (b) (4)	26 Sep 2020 18:05:17

US3342286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User entered 'mmHg'	System	26 Sep 2020 18:05:17

US3342286

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:36:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:32
User entered 'No (N)'	Darrell O'Brien (b) (4)	26 Sep 2020 17:06:13

US3342286

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:36:11

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:32
User entered empty.	(b) (4) Darrell O'Brien (b) (4)	26 Sep 2020 17:06:13

US3342286

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:36:11

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:32
User entered 'Yes (Y)'	Darrell O'Brien (b) (4)	26 Sep 2020 17:24:07

US3342286

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:36:11

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:32
User entered empty.	(b) (4) Darrell O'Brien (b) (4)	26 Sep 2020 17:24:07

US3342286

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:36:11

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 16:13:15
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:32
User entered empty.	Darrell O'Brien (b) (4)	26 Sep 2020 17:24:07

US3342286

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:36:11

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User entered 'MRNA-1273 OR PLACEBO'	System	26 Sep 2020 17:24:07

US3342286

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:36:11

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:32
User entered '26 Sep 2020'	Darrell O'Brien (b) (4)	26 Sep 2020 17:24:07

US3342286

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:32
User entered '12:18'	Darrell O'Brien (b) (4)	26 Sep 2020 17:24:07

US3342286

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User entered '26 Sep 2020 12:18'	System	26 Sep 2020 17:24:07

US3342286

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:32
User entered 'Left Arm (LEFT ARM)'	Darrell O'Brien (b) (4)	26 Sep 2020 17:24:07

US3342286

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User entered 'ONCE'	System	26 Sep 2020 17:24:07

US3342286

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:36:11

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User entered 'INTRAMUSCULAR'	System	26 Sep 2020 17:24:07

US3342286

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:36:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:32
User entered 'Yes (Y)'	Morgan Schulle (b) (4)	28 Sep 2020 18:53:00

US3342286

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:36:11

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:32
User closed query 'Per IMMUNO Lab Recon: GCL has an Unscheduled lab with date of 26SEP2020; however it is recorded in EDC for Visit 1 Day 1. Please confirm collection date of 26SEP2020 is for Visit 1 Day 1 or else clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Nov 2020 09:46:48
Query 'Per IMMUNO Lab Recon: GCL has an Unscheduled lab with date of 26SEP2020; however it is recorded in EDC for Visit 1 Day 1. Please confirm collection date of 26SEP2020 is for Visit 1 Day 1 or else clarify. ' answered with 'COLLECTION DATE OF 26SEP2020 IS FOR VISIT 1' (Site from DM).	Morgan Schulle (b) (4) (b) (4)	05 Oct 2020 16:07:24
User opened query 'Per IMMUNO Lab Recon: GCL has an Unscheduled lab with date of 26SEP2020; however it is recorded in EDC for Visit 1 Day 1. Please confirm collection date of 26SEP2020 is for Visit 1 Day 1 or else clarify. ' (Site from DM).	(b) (4), (b) (6)	04 Oct 2020 08:43:32
User entered '26 Sep 2020'	Morgan Schulle (b) (4) (b) (4)	28 Sep 2020 18:53:00

US3342286

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:36:11

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:32
User entered '12:09'	Morgan Schulle (b) (4)	28 Sep 2020 18:53:00

US3342286

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User entered '26 Sep 2020 12:09'	System	28 Sep 2020 18:53:00

US3342286

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:36:11

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:05
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:32
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 26SEP2020 is recorded under Visit1 Day1 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 10:12:27
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 26SEP2020 is recorded under Visit1 Day1 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' answered with 'The sample reported at 26SEP2020 was collected for Visit 1 Day 1. It is reported as "unscheduled" because an unscheduled lab kit was used due to lab kit shortage.' (Site from DM).	Olivia Hapanowicz (b) (4) (b) (4)	17 Nov 2020 17:30:08
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 26SEP2020 is recorded under Visit1 Day1 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 08:13:36
User entered '26 Sep 2020'	Morgan Schulle (b) (4) (b) (4)	28 Sep 2020 18:53:13

US3342286

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:36:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:05
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Morgan Schulle (b) (4) (b) (4)	28 Sep 2020 18:53:13

US3342286

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:36:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:05
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:32
User entered 'Yes (Y)'	(b) (4) Morgan Schulle (b) (4)	28 Sep 2020 18:53:13

US3342286

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:36:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:05
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:32
User entered '12:10'	Morgan Schulle (b) (4)	28 Sep 2020 18:53:13

US3342286

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:05
User entered '26 Sep 2020 12:10'	System	28 Sep 2020 18:53:13

US3342286

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:36:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:05
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Morgan Schulle (b) (4) (b) (4)	28 Sep 2020 18:53:13

US3342286

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:36:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:05
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:32
User entered 'No (N)'	Morgan Schulle (b) (4)	28 Sep 2020 18:53:13

US3342286

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:36:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:05
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:32
User entered empty.	Morgan Schulle (b) (4)	28 Sep 2020 18:53:13

US3342286

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:36:11

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:05
User entered empty.	System	28 Sep 2020 18:53:13

US3342286

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:32
User entered 'Yes (Y)'	Darrell O'Brien (b) (4)	26 Sep 2020 17:25:04

US3342286

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:36:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:15
User entered 'I'	System	26 Sep 2020 17:25:04

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
Data entry locked.	System	26 Sep 2020 17:24:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:36:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-26T12:52:38', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'fb283552-6359-4180-847b-72414dca8481' User entered 'Yes (Y)'	System	26 Sep 2020 17:52:47
	System	26 Sep 2020 17:52:47

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:36:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-26T12:52:27', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'fb283552-6359-4180-847b-72414dca8481' User entered '98.6'	System	26 Sep 2020 17:52:47
	System	26 Sep 2020 17:52:47

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-26T12:52:33', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'fb283552-6359-4180-847b-72414dca8481'	System	26 Sep 2020 17:52:47
User entered 'No (N)'	System	26 Sep 2020 17:52:47

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:36:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-26T12:52:44', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'fb283552-6359-4180-847b-72414dca8481' User entered '26 Sep 2020 12:52'	System	26 Sep 2020 17:52:47
	System	26 Sep 2020 17:52:47

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:36:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
User entered '26 Sep 2020 12:38'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:36:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
User entered '26 Sep 2020 15:08'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
Data entry locked.	System	26 Sep 2020 17:24:07
User entered 'Day 1, after vaccination (at home)'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:36:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T09:09:20', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'f9f002ee-e8d4-4000-ad7d-86f913aae80d' User entered 'Yes (Y)'	System	27 Sep 2020 14:09:41
	System	27 Sep 2020 14:09:41

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:36:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T09:09:29', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'f9f002ee-e8d4-4000-ad7d-86f913aae80d' User entered '98.5'	System	27 Sep 2020 14:09:41
	System	27 Sep 2020 14:09:41

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T09:09:34', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'f9f002ee-e8d4-4000-ad7d-86f913aae80d' User entered 'No (N)'	System	27 Sep 2020 14:09:41
	System	27 Sep 2020 14:09:41

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:36:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T09:09:39', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'f9f002ee-e8d4-4000-ad7d-86f913aae80d' User entered '27 Sep 2020 09:09'	System	27 Sep 2020 14:09:41
	System	27 Sep 2020 14:09:41

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:36:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
User entered '26 Sep 2020 16:03'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:36:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
User entered '27 Sep 2020 11:59'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
Data entry locked.	System	26 Sep 2020 17:24:07
User entered 'Day 2'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:36:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T15:20:56', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'ac97e859-a27b-44dd-a594-0f97844dce58' User entered 'Yes (Y)'	System	27 Sep 2020 20:21:10
	System	27 Sep 2020 20:21:10

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:36:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T15:21:05', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'ac97e859-a27b-44dd-a594-0f97844dce58' User entered '98.7'	System	27 Sep 2020 20:21:10
	System	27 Sep 2020 20:21:10

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T15:20:40', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'ac97e859-a27b-44dd-a594-0f97844dce58'	System	27 Sep 2020 20:21:10
User entered 'No (N)'	System	27 Sep 2020 20:21:10

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:36:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T15:21:08', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'ac97e859-a27b-44dd-a594-0f97844dce58' User entered '27 Sep 2020 15:21'	System	27 Sep 2020 20:21:10
	System	27 Sep 2020 20:21:10

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:36:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
User entered '27 Sep 2020 12:00'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:36:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
User entered '28 Sep 2020 11:59'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
Data entry locked.	System	26 Sep 2020 17:24:07
User entered 'Day 3'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:36:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-28T16:31:07', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'bdb89629-8e9e-4fbd-aafc-c0c8b85fe0c3' User entered 'No (N)'	System	28 Sep 2020 21:31:19
	System	28 Sep 2020 21:31:19

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-28T16:31:12', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'bdb89629-8e9e-4fbd-aafc-c0c8b85fe0c3' User entered 'No (N)'	System	28 Sep 2020 21:31:19
	System	28 Sep 2020 21:31:19

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:36:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-28T16:31:16', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'bdb89629-8e9e-4fbd-aafc-c0c8b85fe0c3' User entered '28 Sep 2020 16:31'	System	28 Sep 2020 21:31:19
	System	28 Sep 2020 21:31:19

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:36:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
User entered '28 Sep 2020 12:00'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:36:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
User entered '29 Sep 2020 11:59'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
Data entry locked.	System	26 Sep 2020 17:24:07
User entered 'Day 4'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:36:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-29T12:00:14', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'a44014d1-b81c-4219-b62c-5fa84835fc09' User entered 'Yes (Y)'	System	29 Sep 2020 17:00:36
	System	29 Sep 2020 17:00:36

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:36:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-29T12:00:24', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'a44014d1-b81c-4219-b62c-5fa84835fc09' User entered '98.7'	System	29 Sep 2020 17:00:36
	System	29 Sep 2020 17:00:36

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-29T12:00:27', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'a44014d1-b81c-4219-b62c-5fa84835fc09'	System	29 Sep 2020 17:00:36
User entered 'No (N)'	System	29 Sep 2020 17:00:36

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:36:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-29T12:00:29', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'a44014d1-b81c-4219-b62c-5fa84835fc09' User entered '29 Sep 2020 12:00'	System	29 Sep 2020 17:00:36
	System	29 Sep 2020 17:00:36

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:36:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
User entered '29 Sep 2020 12:00'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:36:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
User entered '30 Sep 2020 11:59'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
Data entry locked.	System	26 Sep 2020 17:24:07
User entered 'Day 5'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:36:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-30T22:00:00', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'f2c89dfa-fd59-4e7a-8080-ec4469386184' User entered 'Yes (Y)'	System	01 Oct 2020 03:00:30
	System	01 Oct 2020 03:00:30

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:36:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-30T22:00:09', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'f2c89dfa-fd59-4e7a-8080-ec4469386184' User entered '98.3'	System	01 Oct 2020 03:00:30
	System	01 Oct 2020 03:00:30

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-30T22:00:23', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'f2c89dfa-fd59-4e7a-8080-ec4469386184'	System	01 Oct 2020 03:00:30
User entered 'No (N)'	System	01 Oct 2020 03:00:30

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:36:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-30T22:00:28', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'f2c89dfa-fd59-4e7a-8080-ec4469386184' User entered '30 Sep 2020 22:00'	System	01 Oct 2020 03:00:30
	System	01 Oct 2020 03:00:30

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:36:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
User entered '30 Sep 2020 12:00'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:36:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
User entered '01 Oct 2020 11:59'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
Data entry locked.	System	26 Sep 2020 17:24:07
User entered 'Day 6'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:36:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-10-02T09:41:22', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '1522e0d5-0da7-401d-8f98-0d3b26043153' User entered 'No (N)'	System	02 Oct 2020 14:41:33
	System	02 Oct 2020 14:41:33

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-10-02T09:41:24', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '1522e0d5-0da7-401d-8f98-0d3b26043153'	System	02 Oct 2020 14:41:33
User entered 'No (N)'	System	02 Oct 2020 14:41:33

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:36:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-10-02T09:41:28', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '1522e0d5-0da7-401d-8f98-0d3b26043153' User entered '02 Oct 2020 09:41'	System	02 Oct 2020 14:41:33
	System	02 Oct 2020 14:41:33

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:36:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
User entered '01 Oct 2020 12:00'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:36:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
User entered '02 Oct 2020 11:59'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
Data entry locked.	System	26 Sep 2020 17:24:07
User entered 'Day 7'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:36:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-10-02T23:59:43', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '54bf0452-f158-47fb-9ca6-7937a44a8df5' User entered 'No (N)'	System	03 Oct 2020 05:00:07
	System	03 Oct 2020 05:00:07

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-10-02T23:59:54', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '54bf0452-f158-47fb-9ca6-7937a44a8df5' User entered 'No (N)'	System	03 Oct 2020 05:00:07
	System	03 Oct 2020 05:00:07

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:36:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-10-02T23:59:59', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '54bf0452-f158-47fb-9ca6-7937a44a8df5' User entered '02 Oct 2020 23:59'	System	03 Oct 2020 05:00:07
	System	03 Oct 2020 05:00:07

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:36:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
User entered '02 Oct 2020 12:00'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:36:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
User entered '03 Oct 2020 11:59'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
Data entry locked.	System	26 Sep 2020 17:24:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:36:11

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 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-26T12:53:01', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '6e1f0361-05ca-465c-80d4-c3ebab958125' User entered 'None (1)'	System	26 Sep 2020 17:53:16
	System	26 Sep 2020 17:53:16

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-26T12:53:04', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '6e1f0361-05ca-465c-80d4-c3ebab958125' User entered 'No (N)'	System	26 Sep 2020 17:53:16
	System	26 Sep 2020 17:53:16

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-26T12:53:06', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '6e1f0361-05ca-465c-80d4-c3ebab958125' User entered 'No (N)'	System	26 Sep 2020 17:53:16
	System	26 Sep 2020 17:53:16

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:36:11

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 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-26T12:53:09', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '6e1f0361-05ca-465c-80d4-c3ebab958125' User entered 'None (1)'	System	26 Sep 2020 17:53:16
	System	26 Sep 2020 17:53:16

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:36:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-26T12:53:12', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '6e1f0361-05ca-465c-80d4-c3ebab958125' User entered '26 Sep 2020 12:53'	System	26 Sep 2020 17:53:16
	System	26 Sep 2020 17:53:16

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:36:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
User entered '26 Sep 2020 12:38'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:36:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
User entered '26 Sep 2020 15:08'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
Data entry locked.	System	26 Sep 2020 17:24:07
User entered 'Day 1, after vaccination (at home)'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:36:11

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 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T09:09:59', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'cb811ca7-bb28-40b6-954d-d17cee540efc'	System	27 Sep 2020 14:10:18
User entered 'None (1)'	System	27 Sep 2020 14:10:18

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T09:10:01', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'cb811ca7-bb28-40b6-954d-d17cee540efc' User entered 'No (N)'	System	27 Sep 2020 14:10:18
	System	27 Sep 2020 14:10:18

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T09:10:04', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'cb811ca7-bb28-40b6-954d-d17cee540efc' User entered 'No (N)'	System	27 Sep 2020 14:10:18
	System	27 Sep 2020 14:10:18

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:36:11

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 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T09:10:10', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'cb811ca7-bb28-40b6-954d-d17cee540efc' User entered 'None (1)'	System	27 Sep 2020 14:10:18
	System	27 Sep 2020 14:10:18

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:36:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T09:10:13', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'cb811ca7-bb28-40b6-954d-d17cee540efc' User entered '27 Sep 2020 09:10'	System	27 Sep 2020 14:10:18
	System	27 Sep 2020 14:10:18

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:36:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
User entered '26 Sep 2020 16:03'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:36:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
User entered '27 Sep 2020 11:59'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
Data entry locked.	System	26 Sep 2020 17:24:07
User entered 'Day 2'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:36:11

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 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T15:21:41', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'fe295264-7eb8-4d90-9b5d-347c73b05d7f'	System	27 Sep 2020 20:21:58
User entered 'Does not interfere with activity (2)'	System	27 Sep 2020 20:21:58

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:36:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T15:21:45', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'fe295264-7eb8-4d90-9b5d-347c73b05d7f' User entered 'No (N)'	System	27 Sep 2020 20:21:58
	System	27 Sep 2020 20:21:58

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T15:21:48', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'fe295264-7eb8-4d90-9b5d-347c73b05d7f' User entered 'No (N)'	System	27 Sep 2020 20:21:58
	System	27 Sep 2020 20:21:58

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:36:11

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 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T15:21:51', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'fe295264-7eb8-4d90-9b5d-347c73b05d7f' User entered 'None (1)'	System	27 Sep 2020 20:21:58
	System	27 Sep 2020 20:21:58

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:36:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T15:21:54', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'fe295264-7eb8-4d90-9b5d-347c73b05d7f' User entered '27 Sep 2020 15:21'	System	27 Sep 2020 20:21:58
	System	27 Sep 2020 20:21:58

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:36:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
User entered '27 Sep 2020 12:00'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:36:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
User entered '28 Sep 2020 11:59'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
Data entry locked.	System	26 Sep 2020 17:24:07
User entered 'Day 3'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:36:11

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 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-28T16:31:29', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '16dc52ad-ccfc-4186-bfd7-301f2e7f0481'	System	28 Sep 2020 21:31:45
User entered 'Does not interfere with activity (2)'	System	28 Sep 2020 21:31:45

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:36:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-28T16:31:33', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '16dc52ad-ccfc-4186-bfd7-301f2e7f0481' User entered 'No (N)'	System	28 Sep 2020 21:31:45
	System	28 Sep 2020 21:31:45

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-28T16:31:36', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '16dc52ad-ccfc-4186-bfd7-301f2e7f0481' User entered 'No (N)'	System	28 Sep 2020 21:31:45
	System	28 Sep 2020 21:31:45

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:36:11

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 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-28T16:31:39', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '16dc52ad-ccfc-4186-bfd7-301f2e7f0481' User entered 'None (1)'	System	28 Sep 2020 21:31:45
	System	28 Sep 2020 21:31:45

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:36:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-28T16:31:42', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '16dc52ad-ccfc-4186-bfd7-301f2e7f0481' User entered '28 Sep 2020 16:31'	System	28 Sep 2020 21:31:45
	System	28 Sep 2020 21:31:45

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:36:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
User entered '28 Sep 2020 12:00'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:36:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
User entered '29 Sep 2020 11:59'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
Data entry locked.	System	26 Sep 2020 17:24:07
User entered 'Day 4'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:36:11

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 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-29T12:00:34', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'a011e6d2-ab3b-4f05-ae5f-7eddaf67d85a' User entered 'None (1)'	System	29 Sep 2020 17:01:18
	System	29 Sep 2020 17:01:18

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:36:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-29T12:00:53', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'a011e6d2-ab3b-4f05-ae5f-7eddaf67d85a' User entered 'No (N)'	System	29 Sep 2020 17:01:18
	System	29 Sep 2020 17:01:18

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-29T12:00:55', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'a011e6d2-ab3b-4f05-ae5f-7eddaf67d85a' User entered 'No (N)'	System	29 Sep 2020 17:01:18
	System	29 Sep 2020 17:01:18

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:36:11

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 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-29T12:00:58', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'a011e6d2-ab3b-4f05-ae5f-7eddaf67d85a' User entered 'None (1)'	System	29 Sep 2020 17:01:18
	System	29 Sep 2020 17:01:18

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:36:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-29T12:01:01', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'a011e6d2-ab3b-4f05-ae5f-7eddaf67d85a' User entered '29 Sep 2020 12:01'	System	29 Sep 2020 17:01:18
	System	29 Sep 2020 17:01:18

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:36:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
User entered '29 Sep 2020 12:00'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:36:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
User entered '30 Sep 2020 11:59'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
Data entry locked.	System	26 Sep 2020 17:24:07
User entered 'Day 5'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:36:11

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 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-30T22:00:37', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '8726293b-afa8-4088-8338-7c01c68a2972'	System	01 Oct 2020 03:01:30
User entered 'None (1)'	System	01 Oct 2020 03:01:30

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-30T22:00:42', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '8726293b-afa8-4088-8338-7c01c68a2972' User entered 'No (N)'	System	01 Oct 2020 03:01:30
	System	01 Oct 2020 03:01:30

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-30T22:00:48', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '8726293b-afa8-4088-8338-7c01c68a2972'	System	01 Oct 2020 03:01:30
User entered 'No (N)'	System	01 Oct 2020 03:01:30

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:36:11

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 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-30T22:00:53', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '8726293b-afa8-4088-8338-7c01c68a2972'	System	01 Oct 2020 03:01:30
User entered 'None (1)'	System	01 Oct 2020 03:01:30

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:36:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-30T22:01:28', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '8726293b-afa8-4088-8338-7c01c68a2972'	System	01 Oct 2020 03:01:30
User entered '30 Sep 2020 22:01'	System	01 Oct 2020 03:01:30

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:36:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
User entered '30 Sep 2020 12:00'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:36:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
User entered '01 Oct 2020 11:59'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
Data entry locked.	System	26 Sep 2020 17:24:07
User entered 'Day 6'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:36:11

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 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-10-02T09:41:31', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '27f27050-a6a9-46c1-ad30-321021067e5d' User entered 'None (1)'	System	02 Oct 2020 14:41:44
	System	02 Oct 2020 14:41:44

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:36:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-10-02T09:41:34', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '27f27050-a6a9-46c1-ad30-321021067e5d' User entered 'No (N)'	System	02 Oct 2020 14:41:44
	System	02 Oct 2020 14:41:44

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-10-02T09:41:36', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '27f27050-a6a9-46c1-ad30-321021067e5d' User entered 'No (N)'	System	02 Oct 2020 14:41:44
	System	02 Oct 2020 14:41:44

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:36:11

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 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-10-02T09:41:38', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '27f27050-a6a9-46c1-ad30-321021067e5d' User entered 'None (1)'	System	02 Oct 2020 14:41:44
	System	02 Oct 2020 14:41:44

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:36:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-10-02T09:41:40', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '27f27050-a6a9-46c1-ad30-321021067e5d' User entered '02 Oct 2020 09:41'	System	02 Oct 2020 14:41:44
	System	02 Oct 2020 14:41:44

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:36:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
User entered '01 Oct 2020 12:00'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:36:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
User entered '02 Oct 2020 11:59'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
Data entry locked.	System	26 Sep 2020 17:24:07
User entered 'Day 7'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:36:11

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 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-10-03T00:00:06', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'ba40a5e5-7fb5-42dc-8a61-29fb09ca8223'	System	03 Oct 2020 05:00:40
User entered 'None (1)'	System	03 Oct 2020 05:00:40

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-10-03T00:00:09', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'ba40a5e5-7fb5-42dc-8a61-29fb09ca8223' User entered 'No (N)'	System	03 Oct 2020 05:00:40
	System	03 Oct 2020 05:00:40

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-10-03T00:00:11', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'ba40a5e5-7fb5-42dc-8a61-29fb09ca8223' User entered 'No (N)'	System	03 Oct 2020 05:00:40
	System	03 Oct 2020 05:00:40

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:36:11

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 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-10-03T00:00:28', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'ba40a5e5-7fb5-42dc-8a61-29fb09ca8223'	System	03 Oct 2020 05:00:40
User entered 'None (1)'	System	03 Oct 2020 05:00:40

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:36:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-10-03T00:00:34', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'ba40a5e5-7fb5-42dc-8a61-29fb09ca8223' User entered '03 Oct 2020 00:00'	System	03 Oct 2020 05:00:40
	System	03 Oct 2020 05:00:40

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:36:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
User entered '02 Oct 2020 12:00'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:36:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
User entered '03 Oct 2020 11:59'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
Data entry locked.	System	26 Sep 2020 17:24:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:36:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-26T12:53:19', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'a18b3203-c52c-41a0-9faa-0988b6ca94f3' User entered 'None (0)'	System	26 Sep 2020 17:53:46
	System	26 Sep 2020 17:53:46

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:36:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-26T12:53:21', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'a18b3203-c52c-41a0-9faa-0988b6ca94f3' User entered 'None (0)'	System	26 Sep 2020 17:53:46
	System	26 Sep 2020 17:53:46

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:36:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-26T12:53:23', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'a18b3203-c52c-41a0-9faa-0988b6ca94f3' User entered 'None (0)'	System	26 Sep 2020 17:53:46
	System	26 Sep 2020 17:53:46

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:36:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-26T12:53:26', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'a18b3203-c52c-41a0-9faa-0988b6ca94f3' User entered 'None (0)'	System	26 Sep 2020 17:53:46
	System	26 Sep 2020 17:53:46

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:36:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-26T12:53:30', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'a18b3203-c52c-41a0-9faa-0988b6ca94f3' User entered 'None (0)'	System	26 Sep 2020 17:53:46
	System	26 Sep 2020 17:53:46

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:36:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-26T12:53:33', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'a18b3203-c52c-41a0-9faa-0988b6ca94f3' User entered 'None (0)'	System	26 Sep 2020 17:53:46
	System	26 Sep 2020 17:53:46

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:36:11

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 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-26T12:53:40', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'a18b3203-c52c-41a0-9faa-0988b6ca94f3' User entered 'No (N)'	System	26 Sep 2020 17:53:46
	System	26 Sep 2020 17:53:46

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:36:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-26T12:53:42', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'a18b3203-c52c-41a0-9faa-0988b6ca94f3' User entered '26 Sep 2020 12:53'	System	26 Sep 2020 17:53:46
	System	26 Sep 2020 17:53:46

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:36:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
User entered '26 Sep 2020 12:38'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:36:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
User entered '26 Sep 2020 15:08'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
Data entry locked.	System	26 Sep 2020 17:24:07
User entered 'Day 1, after vaccination (at home)'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:36:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T09:10:18', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'f1ea0059-06fd-4c07-8f84-557ee065f47d' User entered 'None (0)'	System	27 Sep 2020 14:10:50
	System	27 Sep 2020 14:10:50

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:36:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T09:10:23', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'f1ea0059-06fd-4c07-8f84-557ee065f47d'	System	27 Sep 2020 14:10:50
User entered 'Some interference with activity (2)'	System	27 Sep 2020 14:10:50

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:36:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T09:10:32', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'f1ea0059-06fd-4c07-8f84-557ee065f47d' User entered 'Some interference with activity (2)'	System	27 Sep 2020 14:10:50
	System	27 Sep 2020 14:10:50

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:36:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T09:10:35', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'f1ea0059-06fd-4c07-8f84-557ee065f47d' User entered 'None (0)'	System	27 Sep 2020 14:10:50
	System	27 Sep 2020 14:10:50

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:36:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T09:10:39', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'f1ea0059-06fd-4c07-8f84-557ee065f47d' User entered 'None (0)'	System	27 Sep 2020 14:10:50
	System	27 Sep 2020 14:10:50

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:36:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T09:10:41', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'f1ea0059-06fd-4c07-8f84-557ee065f47d' User entered 'None (0)'	System	27 Sep 2020 14:10:50
	System	27 Sep 2020 14:10:50

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:36:11

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 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T09:10:45', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'f1ea0059-06fd-4c07-8f84-557ee065f47d' User entered 'No (N)'	System	27 Sep 2020 14:10:50
	System	27 Sep 2020 14:10:50

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:36:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T09:10:47', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'f1ea0059-06fd-4c07-8f84-557ee065f47d' User entered '27 Sep 2020 09:10'	System	27 Sep 2020 14:10:50
	System	27 Sep 2020 14:10:50

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:36:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
User entered '26 Sep 2020 16:03'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:36:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
User entered '27 Sep 2020 11:59'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
Data entry locked.	System	26 Sep 2020 17:24:07
User entered 'Day 2'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:36:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T15:21:59', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '70f3e895-e73b-4c4e-be49-09f0a8cc0852' User entered 'None (0)'	System	27 Sep 2020 20:22:47
	System	27 Sep 2020 20:22:47

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:36:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T15:22:09', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '70f3e895-e73b-4c4e-be49-09f0a8cc0852' User entered 'None (0)'	System	27 Sep 2020 20:22:47
	System	27 Sep 2020 20:22:47

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:36:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T15:22:17', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '70f3e895-e73b-4c4e-be49-09f0a8cc0852'	System	27 Sep 2020 20:22:47
User entered 'No interference with activity (1)'	System	27 Sep 2020 20:22:47

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:36:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T15:22:29', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '70f3e895-e73b-4c4e-be49-09f0a8cc0852'	System	27 Sep 2020 20:22:47
User entered 'No interference with activity (1)'	System	27 Sep 2020 20:22:47

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:36:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T15:22:32', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '70f3e895-e73b-4c4e-be49-09f0a8cc0852' User entered 'None (0)'	System	27 Sep 2020 20:22:47
	System	27 Sep 2020 20:22:47

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:36:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T15:22:35', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '70f3e895-e73b-4c4e-be49-09f0a8cc0852' User entered 'None (0)'	System	27 Sep 2020 20:22:47
	System	27 Sep 2020 20:22:47

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:36:11

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 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T15:22:43', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '70f3e895-e73b-4c4e-be49-09f0a8cc0852'	System	27 Sep 2020 20:22:47
User entered 'No (N)'	System	27 Sep 2020 20:22:47

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:36:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-27T15:22:45', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '70f3e895-e73b-4c4e-be49-09f0a8cc0852'	System	27 Sep 2020 20:22:47
User entered '27 Sep 2020 15:22'	System	27 Sep 2020 20:22:47

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:36:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
User entered '27 Sep 2020 12:00'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:36:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
User entered '28 Sep 2020 11:59'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
Data entry locked.	System	26 Sep 2020 17:24:07
User entered 'Day 3'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:36:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-28T16:31:47', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'df3781f8-5916-4749-a588-097708f73e5c'	System	28 Sep 2020 21:32:18
User entered 'No interference with activity (1)'	System	28 Sep 2020 21:32:18

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:36:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-28T16:31:50', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'df3781f8-5916-4749-a588-097708f73e5c'	System	28 Sep 2020 21:32:18
User entered 'No interference with activity (1)'	System	28 Sep 2020 21:32:18

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:36:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-28T16:31:54', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'df3781f8-5916-4749-a588-097708f73e5c' User entered 'Some interference with activity (2)'	System	28 Sep 2020 21:32:18
	System	28 Sep 2020 21:32:18

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:36:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-28T16:31:59', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'df3781f8-5916-4749-a588-097708f73e5c'	System	28 Sep 2020 21:32:18
User entered 'No interference with activity (1)'	System	28 Sep 2020 21:32:18

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:36:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-28T16:32:05', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'df3781f8-5916-4749-a588-097708f73e5c'	System	28 Sep 2020 21:32:18
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	28 Sep 2020 21:32:18

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:36:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-28T16:32:08', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'df3781f8-5916-4749-a588-097708f73e5c'	System	28 Sep 2020 21:32:18
User entered 'No interference with activity (1)'	System	28 Sep 2020 21:32:18

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:36:11

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 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-28T16:32:12', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'df3781f8-5916-4749-a588-097708f73e5c' User entered 'No (N)'	System	28 Sep 2020 21:32:18
	System	28 Sep 2020 21:32:18

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:36:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-28T16:32:14', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'df3781f8-5916-4749-a588-097708f73e5c' User entered '28 Sep 2020 16:32'	System	28 Sep 2020 21:32:18
	System	28 Sep 2020 21:32:18

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:36:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
User entered '28 Sep 2020 12:00'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:36:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
User entered '29 Sep 2020 11:59'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
Data entry locked.	System	26 Sep 2020 17:24:07
User entered 'Day 4'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:36:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-29T12:01:04', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '26833015-35a4-4c80-9602-59c25862277e' User entered 'None (0)'	System	29 Sep 2020 17:01:40
	System	29 Sep 2020 17:01:40

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:36:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-29T12:01:06', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '26833015-35a4-4c80-9602-59c25862277e' User entered 'None (0)'	System	29 Sep 2020 17:01:40
	System	29 Sep 2020 17:01:40

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:36:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-29T12:01:07', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '26833015-35a4-4c80-9602-59c25862277e' User entered 'None (0)'	System	29 Sep 2020 17:01:40
	System	29 Sep 2020 17:01:40

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:36:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-29T12:01:10', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '26833015-35a4-4c80-9602-59c25862277e' User entered 'None (0)'	System	29 Sep 2020 17:01:40
	System	29 Sep 2020 17:01:40

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:36:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-29T12:01:12', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '26833015-35a4-4c80-9602-59c25862277e' User entered 'None (0)'	System	29 Sep 2020 17:01:40
	System	29 Sep 2020 17:01:40

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:36:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-29T12:01:14', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '26833015-35a4-4c80-9602-59c25862277e' User entered 'None (0)'	System	29 Sep 2020 17:01:40
	System	29 Sep 2020 17:01:40

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:36:11

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 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-29T12:01:17', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '26833015-35a4-4c80-9602-59c25862277e' User entered 'No (N)'	System	29 Sep 2020 17:01:40
	System	29 Sep 2020 17:01:40

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:36:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-29T12:01:19', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '26833015-35a4-4c80-9602-59c25862277e' User entered '29 Sep 2020 12:01'	System	29 Sep 2020 17:01:40
	System	29 Sep 2020 17:01:40

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:36:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
User entered '29 Sep 2020 12:00'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:36:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
User entered '30 Sep 2020 11:59'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
Data entry locked.	System	26 Sep 2020 17:24:07
User entered 'Day 5'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:36:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-30T22:01:32', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '2242ce3d-aade-4257-b032-d3ec066d55ed' User entered 'None (0)'	System	01 Oct 2020 03:01:59
	System	01 Oct 2020 03:01:59

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:36:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-30T22:01:35', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '2242ce3d-aade-4257-b032-d3ec066d55ed' User entered 'None (0)'	System	01 Oct 2020 03:01:59
	System	01 Oct 2020 03:01:59

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:36:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-30T22:01:40', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '2242ce3d-aade-4257-b032-d3ec066d55ed' User entered 'None (0)'	System	01 Oct 2020 03:01:59
	System	01 Oct 2020 03:01:59

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:36:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-30T22:01:47', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '2242ce3d-aade-4257-b032-d3ec066d55ed' User entered 'None (0)'	System	01 Oct 2020 03:01:59
	System	01 Oct 2020 03:01:59

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:36:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-30T22:01:49', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '2242ce3d-aade-4257-b032-d3ec066d55ed' User entered 'None (0)'	System	01 Oct 2020 03:01:59
	System	01 Oct 2020 03:01:59

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:36:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-30T22:01:51', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '2242ce3d-aade-4257-b032-d3ec066d55ed' User entered 'None (0)'	System	01 Oct 2020 03:01:59
	System	01 Oct 2020 03:01:59

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:36:11

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 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-30T22:01:55', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '2242ce3d-aade-4257-b032-d3ec066d55ed' User entered 'No (N)'	System	01 Oct 2020 03:01:59
	System	01 Oct 2020 03:01:59

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:36:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-09-30T22:01:58', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '2242ce3d-aade-4257-b032-d3ec066d55ed' User entered '30 Sep 2020 22:01'	System	01 Oct 2020 03:01:59
	System	01 Oct 2020 03:01:59

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:36:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
User entered '30 Sep 2020 12:00'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:36:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
User entered '01 Oct 2020 11:59'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
Data entry locked.	System	26 Sep 2020 17:24:07
User entered 'Day 6'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:36:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-10-02T09:41:43', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'eda6c25e-21db-4698-a03c-62872187cc13' User entered 'None (0)'	System	02 Oct 2020 14:41:59
	System	02 Oct 2020 14:41:59

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:36:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-10-02T09:41:44', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'eda6c25e-21db-4698-a03c-62872187cc13' User entered 'None (0)'	System	02 Oct 2020 14:41:59
	System	02 Oct 2020 14:41:59

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:36:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-10-02T09:41:46', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'eda6c25e-21db-4698-a03c-62872187cc13' User entered 'None (0)'	System	02 Oct 2020 14:41:59
	System	02 Oct 2020 14:41:59

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:36:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-10-02T09:41:48', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'eda6c25e-21db-4698-a03c-62872187cc13' User entered 'None (0)'	System	02 Oct 2020 14:41:59
	System	02 Oct 2020 14:41:59

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:36:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-10-02T09:41:50', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'eda6c25e-21db-4698-a03c-62872187cc13' User entered 'None (0)'	System	02 Oct 2020 14:41:59
	System	02 Oct 2020 14:41:59

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:36:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-10-02T09:41:52', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'eda6c25e-21db-4698-a03c-62872187cc13' User entered 'None (0)'	System	02 Oct 2020 14:41:59
	System	02 Oct 2020 14:41:59

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:36:11

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 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-10-02T09:41:55', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'eda6c25e-21db-4698-a03c-62872187cc13' User entered 'No (N)'	System	02 Oct 2020 14:41:59
	System	02 Oct 2020 14:41:59

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:36:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-10-02T09:41:57', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'eda6c25e-21db-4698-a03c-62872187cc13' User entered '02 Oct 2020 09:41'	System	02 Oct 2020 14:41:59
	System	02 Oct 2020 14:41:59

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:36:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
User entered '01 Oct 2020 12:00'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:36:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
User entered '02 Oct 2020 11:59'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
Data entry locked.	System	26 Sep 2020 17:24:07
User entered 'Day 7'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:36:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-10-03T00:00:38', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'fbe67b52-23a0-4e94-8394-196b48a65c6b' User entered 'None (0)'	System	03 Oct 2020 05:01:37
	System	03 Oct 2020 05:01:37

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:36:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-10-03T00:00:40', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'fbe67b52-23a0-4e94-8394-196b48a65c6b' User entered 'None (0)'	System	03 Oct 2020 05:01:37
	System	03 Oct 2020 05:01:37

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:36:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-10-03T00:00:44', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'fbe67b52-23a0-4e94-8394-196b48a65c6b' User entered 'None (0)'	System	03 Oct 2020 05:01:37
	System	03 Oct 2020 05:01:37

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:36:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-10-03T00:00:54', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'fbe67b52-23a0-4e94-8394-196b48a65c6b' User entered 'None (0)'	System	03 Oct 2020 05:01:37
	System	03 Oct 2020 05:01:37

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:36:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-10-03T00:01:08', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'fbe67b52-23a0-4e94-8394-196b48a65c6b' User entered 'None (0)'	System	03 Oct 2020 05:01:37
	System	03 Oct 2020 05:01:37

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:36:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-10-03T00:01:18', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'fbe67b52-23a0-4e94-8394-196b48a65c6b' User entered 'None (0)'	System	03 Oct 2020 05:01:37
	System	03 Oct 2020 05:01:37

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:36:11

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 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-10-03T00:01:30', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'fbe67b52-23a0-4e94-8394-196b48a65c6b' User entered 'No (N)'	System	03 Oct 2020 05:01:37
	System	03 Oct 2020 05:01:37

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:36:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-10-03T00:01:34', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'fbe67b52-23a0-4e94-8394-196b48a65c6b' User entered '03 Oct 2020 00:01'	System	03 Oct 2020 05:01:37
	System	03 Oct 2020 05:01:37

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:36:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
User entered '02 Oct 2020 12:00'	System	26 Sep 2020 17:24:07

US3342286

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:36:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:39:29
User entered '03 Oct 2020 11:59'	System	26 Sep 2020 17:24:07

US3342286

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:05
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:38:52

US3342286

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:05
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:32
User entered '5 Oct 2020'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:38:52

US3342286

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:05
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:32
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:38:52

US3342286

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:05
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:32
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 19:38:52

US3342286

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:05
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:38:44

US3342286

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:05
User entered 'I'	System	05 Oct 2020 19:38:44

US3342286

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:05
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 18:49:45

US3342286

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:05
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:32
User entered '12 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 18:49:45

US3342286

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:05
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:32
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 18:49:45

US3342286

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:05
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:32
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 18:49:45

US3342286

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:05
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 18:49:51

US3342286

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 16:13:05
User entered 'I'	System	12 Oct 2020 18:49:51

US3342286

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:49
Data entry locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:31:03

US3342286

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:11

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:49
Data entry locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:32
User entered '19 Oct 2020'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:31:03

US3342286

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:49
Data entry locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:32
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:31:03

US3342286

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:49
Data entry locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:32
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 21:31:03

US3342286

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:49
Data entry locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:22
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 21:31:09

US3342286

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:01:49
Data entry locked.	(b) (4), (b) (6)	29 Apr 2021 11:58:22
User entered 'I'	System	19 Oct 2020 21:31:09

US3342286

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:36:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered 'Yes (Y)'	John Luna (b) (4)	26 Oct 2020 20:38:41

US3342286

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered '26 Oct 2020'	John Luna (b) (4)	26 Oct 2020 20:38:41

US3342286

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:36:11

[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 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered 'Clinic (Clinic)'	John Luna (b) (4)	26 Oct 2020 20:38:41

US3342286

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:36:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User entered 'VISIT2'	System	26 Oct 2020 20:38:41

US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User accepted default value 'Pre-Dose (PREDOSE)'	John Luna (b) (4)	26 Oct 2020 20:39:33

US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered 'Yes (Y)'	John Luna (b) (4)	26 Oct 2020 20:39:33

US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered '26 Oct 2020'	John Luna (b) (4)	26 Oct 2020 20:39:33

US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered '13:50'	John Luna (b) (4)	26 Oct 2020 20:39:33

US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User entered '26 Oct 2020 13:50'	System	26 Oct 2020 20:39:33

US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered '98.3' F	John Luna (b) (4)	26 Oct 2020 20:39:33

US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered 'Oral (Oral)'	John Luna (b) (4)	26 Oct 2020 20:39:33

US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered empty.	John Luna (b) (4)	26 Oct 2020 20:39:33

US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered '83'	John Luna (b) (4)	26 Oct 2020 20:39:33

US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User entered 'bpm'	System	26 Oct 2020 20:39:33

US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered '12'	John Luna (b) (4)	26 Oct 2020 20:39:33

US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User entered 'breaths/min'	System	26 Oct 2020 20:39:33

US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered '181'	John Luna (b) (4)	26 Oct 2020 20:39:33

US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User entered 'mmHg'	System	26 Oct 2020 20:39:33

US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:05:15
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'CS per investigator. Subject discontinued from treatment and will follow up with PCP and continue all other study assessments per protocol.' (Site from System).	John Luna (b) (4)	26 Oct 2020 20:40:38
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		26 Oct 2020 20:39:33
User entered '127'	John Luna (b) (4)	26 Oct 2020 20:39:33

US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:36:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User entered 'mmHg'	System	26 Oct 2020 20:39:33

US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User accepted default value 'Post-Dose (POSTDOSE)'	John Luna (b) (4)	26 Oct 2020 20:39:33

US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered 'No (N)'	John Luna (b) (4)	26 Oct 2020 20:39:33

US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered empty.	John Luna (b) (4)	26 Oct 2020 20:39:33

US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered empty.	John Luna (b) (4)	26 Oct 2020 20:39:33

US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User entered empty.	System	26 Oct 2020 20:39:33

US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered empty.	John Luna (b) (4)	26 Oct 2020 20:39:33

US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered empty.	John Luna (b) (4)	26 Oct 2020 20:39:33

US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered empty.	John Luna (b) (4)	26 Oct 2020 20:39:33

US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered empty.	John Luna (b) (4)	26 Oct 2020 20:39:33

US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User entered empty.	System	26 Oct 2020 20:39:33

US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered empty.	John Luna (b) (4)	26 Oct 2020 20:39:33

US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User entered empty.	System	26 Oct 2020 20:39:33

US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered empty.	John Luna (b) (4)	26 Oct 2020 20:39:33

US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User entered empty.	System	26 Oct 2020 20:39:33

US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered empty.	John Luna (b) (4)	26 Oct 2020 20:39:33

US3342286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:36:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User entered empty.	System	26 Oct 2020 20:39:33

US3342286

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:36:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered 'Yes (Y)'	John Luna (b) (4)	26 Oct 2020 20:40:46

US3342286

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:36:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered '26 Oct 2020'	John Luna (b) (4)	26 Oct 2020 20:40:46

US3342286

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:36:11

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered 'No (N)'	John Luna (b) (4)	26 Oct 2020 20:41:11

US3342286

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:36:11

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)'	John Luna (b) (4)	26 Oct 2020 20:41:11

US3342286

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:36:11

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 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered empty.	John Luna (b) (4)	26 Oct 2020 20:41:11

US3342286

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:36:11

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User entered empty.	System	26 Oct 2020 20:41:11

US3342286

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:36:11

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered empty.	John Luna (b) (4)	26 Oct 2020 20:41:11

US3342286

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered empty.	John Luna (b) (4)	26 Oct 2020 20:41:11

US3342286

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User entered empty.	System	26 Oct 2020 20:41:11

US3342286

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered empty.	John Luna (b) (4)	26 Oct 2020 20:41:11

US3342286

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:36:11

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User entered empty.	System	26 Oct 2020 20:41:11

US3342286

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:36:11

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User entered empty.	System	26 Oct 2020 20:41:11

US3342286

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:36:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered 'Yes (Y)'	(b) (4) Morgan Schulle (b) (4)	28 Oct 2020 18:58:02

US3342286

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:36:11

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User closed query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit 2 Day 29 is recorded as 26-OCT-2020. However, collection date is missing in GCL. Please confirm if 26-OCT-2020 is correct date to update in GCL records.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Dec 2020 10:32:29
Query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit 2 Day 29 is recorded as 26-OCT-2020. However, collection date is missing in GCL. Please confirm if 26-OCT-2020 is correct date to update in GCL records.' answered with 'Visit 2 Day 29 collection date confirmed as 26-OCT-2020.' (Site from DM).	Andrew Bell (b) (4) (b) (4)	12 Nov 2020 15:24:37
User opened query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit 2 Day 29 is recorded as 26-OCT-2020. However, collection date is missing in GCL. Please confirm if 26-OCT-2020 is correct date to update in GCL records.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 09:52:09
User entered '26 Oct 2020'	Morgan Schulle (b) (4) (b) (4)	28 Oct 2020 18:58:02

US3342286

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:36:11

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered '14:31'	Morgan Schulle (b) (4)	28 Oct 2020 18:58:02

US3342286

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User entered '26 Oct 2020 14:31'	System	28 Oct 2020 18:58:02

US3342286

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:36:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered '26 Oct 2020'	Morgan Schulle (b) (4)	28 Oct 2020 18:58:26

US3342286

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:36:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Morgan Schulle (b) (4) (b) (4)	28 Oct 2020 18:58:26

US3342286

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:36:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered 'Yes (Y)'	(b) (4) Morgan Schulle (b) (4)	28 Oct 2020 18:58:26

US3342286

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:36:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered '14:33'	Morgan Schulle (b) (4)	28 Oct 2020 18:58:26

US3342286

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User entered '26 Oct 2020 14:33'	System	28 Oct 2020 18:58:26

US3342286

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:36:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Morgan Schulle (b) (4) (b) (4)	28 Oct 2020 18:58:26

US3342286

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:36:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered 'No (N)'	Morgan Schulle (b) (4)	28 Oct 2020 18:58:26

US3342286

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:36:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered empty.	Morgan Schulle (b) (4)	28 Oct 2020 18:58:26

US3342286

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:36:11

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User entered empty.	System	28 Oct 2020 18:58:26

US3342286

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered 'Yes (Y)'	John Luna (b) (4)	26 Oct 2020 20:41:24

US3342286

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User entered 'I'	System	26 Oct 2020 20:41:24

US3342286

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:32
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	03 Nov 2020 15:31:51

US3342286

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:32
User entered '3 Nov 2020'	Ethan Shotton (b) (4)	03 Nov 2020 15:31:51

US3342286

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:32
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4)	03 Nov 2020 15:31:51

US3342286

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:32
User entered empty.	Ethan Shotton (b) (4)	03 Nov 2020 15:31:51

US3342286

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:42:08

US3342286

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User entered 'I'	System	09 Nov 2020 16:42:08

US3342286

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:42:19

US3342286

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:32
User entered '9 Nov 2020'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:42:19

US3342286

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:32
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:42:19

US3342286

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:32
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:42:19

US3342286

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 16:42:23

US3342286

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User entered 'I'	System	09 Nov 2020 16:42:23

US3342286

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:56:47

US3342286

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:32
User entered '16 Nov 2020'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:56:47

US3342286

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:32
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:56:47

US3342286

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:32
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:56:47

US3342286

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 21:56:52

US3342286

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User entered 'I'	System	16 Nov 2020 21:56:52

US3342286

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:36:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User closed query 'Per GCL Lab Reconciliation: Per GCL, there is an immunogenicity sample collected on 20NOV2020 for the Visit 3 Day 57 Visit, however, there is no data recorded for the Visit 3 Day 57 Visit. Please clarify and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Jan 2021 06:59:54
Query 'Per GCL Lab Reconciliation: Per GCL, there is an immunogenicity sample collected on 20NOV2020 for the Visit 3 Day 57 Visit, however, there is no data recorded for the Visit 3 Day 57 Visit. Please clarify and update as appropriate. ' answered with 'updated' (Site from DM).	Olivia Hapanowicz (b) (4) (b) (4)	22 Jan 2021 18:36:19
User opened query 'Per GCL Lab Reconciliation: Per GCL, there is an immunogenicity sample collected on 20NOV2020 for the Visit 3 Day 57 Visit, however, there is no data recorded for the Visit 3 Day 57 Visit. Please clarify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 14:45:34
User entered 'Yes (Y)'	Darrell O'Brien (b) (4) (b) (4)	20 Nov 2020 18:15:53

US3342286

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered '20 Nov 2020'	Darrell O'Brien (b) (4)	20 Nov 2020 18:15:53

US3342286

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:36:11

[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 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered 'Clinic (Clinic)'	Darrell O'Brien (b) (4)	20 Nov 2020 18:15:53

US3342286

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:36:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User entered 'VISIT3'	System	20 Nov 2020 18:15:53

US3342286

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered 'Yes (Y)'	(b) (4) Darrell O'Brien (b) (4)	20 Nov 2020 18:16:25

US3342286

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered '20 Nov 2020'	Darrell O'Brien (b) (4)	20 Nov 2020 18:16:25

US3342286

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered '08:46'	Darrell O'Brien (b) (4)	20 Nov 2020 18:16:25

US3342286

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User entered '20 Nov 2020 08:46'	System	20 Nov 2020 18:16:25

US3342286

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered '98.6' F	Darrell O'Brien (b) (4)	20 Nov 2020 18:16:25

US3342286

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered 'Oral (Oral)'	Darrell O'Brien (b) (4)	20 Nov 2020 18:16:25

US3342286

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered empty.	(b) (4) Darrell O'Brien (b) (4)	20 Nov 2020 18:16:25

US3342286

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered '80'	Darrell O'Brien (b) (4)	20 Nov 2020 18:16:25

US3342286

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User entered 'bpm'	System	20 Nov 2020 18:16:25

US3342286

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered '14'	Darrell O'Brien (b) (4)	20 Nov 2020 18:16:25

US3342286

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User entered 'breaths/min'	System	20 Nov 2020 18:16:25

US3342286

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered '174'	Darrell O'Brien (b) (4)	20 Nov 2020 18:16:25

US3342286

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User entered 'mmHg'	System	20 Nov 2020 18:16:25

US3342286

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 13:27:24
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Pt has ongoing AE for unspecified htn' (Site from System).	Darrell O'Brien (b) (4) (b) (4)	20 Nov 2020 18:16:54
User opened query 'Diastolic Blood Pressure reported System is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		20 Nov 2020 18:16:25
User entered '109'	Darrell O'Brien (b) (4) (b) (4)	20 Nov 2020 18:16:25

US3342286

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User entered 'mmHg'	System	20 Nov 2020 18:16:25

US3342286

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48

US3342286

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48

US3342286

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:36:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered 'Yes (Y)'	(b) (4) Darrell O'Brien (b) (4)	20 Nov 2020 18:20:37

US3342286

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:36:11

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered '20 Nov 2020'	Darrell O'Brien (b) (4)	20 Nov 2020 18:20:37

US3342286

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:36:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered 'Yes (Y)'	Olivia Hapanowicz (b) (4)	22 Jan 2021 18:36:09

US3342286

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:36:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered '20 Nov 2020'	Olivia Hapanowicz (b) (4)	22 Jan 2021 18:36:09

US3342286

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:36:11

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered '09:08'	Olivia Hapanowicz (b) (4)	22 Jan 2021 18:36:09

US3342286

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User entered '20 Nov 2020 09:08'	System	22 Jan 2021 18:36:09

US3342286

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:58:37
User entered 'Yes (Y)'	(b) (4) Darrell O'Brien (b) (4)	20 Nov 2020 18:19:09

US3342286

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User entered '1'	System	20 Nov 2020 18:19:09

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-11-25T13:53:44', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '5fe87048-396e-4f64-ac00-6a6c6606d7e5' User entered 'No (N)'	System	25 Nov 2020 19:54:10
	System	25 Nov 2020 19:54:10

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

Have you been exposed to someone with 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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-11-25T13:53:47', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '5fe87048-396e-4f64-ac00-6a6c6606d7e5' User entered 'No (N)'	System	25 Nov 2020 19:54:10
	System	25 Nov 2020 19:54:10

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-11-25T13:53:51', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '5fe87048-396e-4f64-ac00-6a6c6606d7e5' User entered '25 Nov 2020 13:53:51'	System	25 Nov 2020 19:54:10
	System	25 Nov 2020 19:54:10

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '23 Nov 2020 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '27 Nov 2020 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-12-02T12:28:03', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '92c820ff-e1de-4d2d-8399-e297db5edbfef'	System	02 Dec 2020 18:28:11
User entered 'No (N)'	System	02 Dec 2020 18:28:11

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

Have you been exposed to someone with 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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-12-02T12:28:06', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '92c820ff-e1de-4d2d-8399-e297db5edbfe' User entered 'No (N)'	System	02 Dec 2020 18:28:11
	System	02 Dec 2020 18:28:11

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-12-02T12:28:08', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '92c820ff-e1de-4d2d-8399-e297db5edbfe' User entered '02 Dec 2020 12:28:08'	System	02 Dec 2020 18:28:11
	System	02 Dec 2020 18:28:11

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '30 Nov 2020 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '04 Dec 2020 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-12-07T06:56:30', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'fe488a46-d94b-4d0a-8bf5-ad8e790fe7e5'	System	07 Dec 2020 12:56:39
User entered 'No (N)'	System	07 Dec 2020 12:56:39

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

Have you been exposed to someone with 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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-12-07T06:56:33', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'fe488a46-d94b-4d0a-8bf5-ad8e790fe7e5'	System	07 Dec 2020 12:56:39
User entered 'No (N)'	System	07 Dec 2020 12:56:39

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-12-07T06:56:35', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'fe488a46-d94b-4d0a-8bf5-ad8e790fe7e5'	System	07 Dec 2020 12:56:39
User entered '07 Dec 2020 06:56:35'	System	07 Dec 2020 12:56:39

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '07 Dec 2020 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '11 Dec 2020 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-12-14T06:36:45', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '3a679fd0-0791-41db-ab11-1fd96e9a0277' User entered 'No (N)'	System	14 Dec 2020 12:36:59
	System	14 Dec 2020 12:36:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

Have you been exposed to someone with 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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-12-14T06:36:48', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '3a679fd0-0791-41db-ab11-1fd96e9a0277'	System	14 Dec 2020 12:36:59
User entered 'No (N)'	System	14 Dec 2020 12:36:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-12-14T06:36:55', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '3a679fd0-0791-41db-ab11-1fd96e9a0277' User entered '14 Dec 2020 06:36:55'	System	14 Dec 2020 12:36:59
	System	14 Dec 2020 12:36:59

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '14 Dec 2020 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '18 Dec 2020 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-12-21T06:24:34', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'be41960a-311c-4d9b-b777-1f1ce1bf1930' User entered 'No (N)'	System	21 Dec 2020 12:24:41
	System	21 Dec 2020 12:24:41

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

Have you been exposed to someone with 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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-12-21T06:24:36', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'be41960a-311c-4d9b-b777-1f1ce1bf1930'	System	21 Dec 2020 12:24:41
User entered 'No (N)'	System	21 Dec 2020 12:24:41

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-12-21T06:24:38', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'be41960a-311c-4d9b-b777-1f1ce1bf1930' User entered '21 Dec 2020 06:24:38'	System	21 Dec 2020 12:24:41
	System	21 Dec 2020 12:24:41

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '21 Dec 2020 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '25 Dec 2020 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-12-28T08:50:24', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '01410df6-56dd-4791-a31a-81bd93d005c4' User entered 'No (N)'	System	28 Dec 2020 14:50:33
	System	28 Dec 2020 14:50:33

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

Have you been exposed to someone with 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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-12-28T08:50:26', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '01410df6-56dd-4791-a31a-81bd93d005c4'	System	28 Dec 2020 14:50:33
User entered 'No (N)'	System	28 Dec 2020 14:50:33

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2020-12-28T08:50:29', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '01410df6-56dd-4791-a31a-81bd93d005c4' User entered '28 Dec 2020 08:50:29'	System	28 Dec 2020 14:50:33
	System	28 Dec 2020 14:50:33

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '28 Dec 2020 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '01 Jan 2021 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2021-01-04T20:24:04', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '53fb5cdc-8d22-4569-a1fb-2645ff99c24d' User entered 'No (N)'	System	05 Jan 2021 02:24:14
	System	05 Jan 2021 02:24:14

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

Have you been exposed to someone with 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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2021-01-04T20:24:06', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '53fb5cdc-8d22-4569-a1fb-2645ff99c24d'	System	05 Jan 2021 02:24:14
User entered 'No (N)'	System	05 Jan 2021 02:24:14

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2021-01-04T20:24:10', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '53fb5cdc-8d22-4569-a1fb-2645ff99c24d' User entered '04 Jan 2021 20:24:10'	System	05 Jan 2021 02:24:14
	System	05 Jan 2021 02:24:14

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '04 Jan 2021 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '08 Jan 2021 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2021-01-11T14:30:10', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'deeba095-0799-49f9-b93c-bb6f77a129cc' User entered 'No (N)'	System	11 Jan 2021 20:30:22
	System	11 Jan 2021 20:30:22

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

Have you been exposed to someone with 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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2021-01-11T14:30:12', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'deeba095-0799-49f9-b93c-bb6f77a129cc'	System	11 Jan 2021 20:30:22
User entered 'No (N)'	System	11 Jan 2021 20:30:22

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2021-01-11T14:30:17', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'deeba095-0799-49f9-b93c-bb6f77a129cc'	System	11 Jan 2021 20:30:22
User entered '11 Jan 2021 14:30:17'	System	11 Jan 2021 20:30:22

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '11 Jan 2021 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '15 Jan 2021 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2021-01-18T23:12:49', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '1d2a5b88-a5b8-4516-b251-bcc67a898795'	System	19 Jan 2021 05:12:56
User entered 'No (N)'	System	19 Jan 2021 05:12:56

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

Have you been exposed to someone with 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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2021-01-18T23:12:52', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '1d2a5b88-a5b8-4516-b251-bcc67a898795'	System	19 Jan 2021 05:12:56
User entered 'No (N)'	System	19 Jan 2021 05:12:56

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2021-01-18T23:12:54', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '1d2a5b88-a5b8-4516-b251-bcc67a898795' User entered '18 Jan 2021 23:12:54'	System	19 Jan 2021 05:12:56
	System	19 Jan 2021 05:12:56

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '18 Jan 2021 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '22 Jan 2021 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2021-01-25T06:35:23', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '24a164f4-9d68-40dd-a14f-cd905a614fff' User entered 'No (N)'	System	25 Jan 2021 12:35:31
	System	25 Jan 2021 12:35:31

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

Have you been exposed to someone with 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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2021-01-25T06:35:25', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '24a164f4-9d68-40dd-a14f-cd905a614fff'	System	25 Jan 2021 12:35:31
User entered 'No (N)'	System	25 Jan 2021 12:35:31

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2021-01-25T06:35:27', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '24a164f4-9d68-40dd-a14f-cd905a614fff' User entered '25 Jan 2021 06:35:27'	System	25 Jan 2021 12:35:31

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '25 Jan 2021 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '29 Jan 2021 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2021-02-01T00:01:28', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'a1d3b061-447b-4395-8cca-384be6da5aeb' User entered 'No (N)'	System	01 Feb 2021 06:01:38
	System	01 Feb 2021 06:01:38

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

Have you been exposed to someone with 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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2021-02-01T00:01:32', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'a1d3b061-447b-4395-8cca-384be6da5aeb' User entered 'No (N)'	System	01 Feb 2021 06:01:38
	System	01 Feb 2021 06:01:38

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2021-02-01T00:01:34', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'a1d3b061-447b-4395-8cca-384be6da5aeb' User entered '01 Feb 2021 00:01:34'	System	01 Feb 2021 06:01:38
	System	01 Feb 2021 06:01:38

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '01 Feb 2021 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '05 Feb 2021 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2021-02-08T16:12:36', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '06406f8d-9491-4caf-94f4-871eb82a55bd' User entered 'No (N)'	System	08 Feb 2021 22:13:03
	System	08 Feb 2021 22:13:03

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

Have you been exposed to someone with 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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2021-02-08T16:12:57', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '06406f8d-9491-4caf-94f4-871eb82a55bd' User entered 'No (N)'	System	08 Feb 2021 22:13:03
	System	08 Feb 2021 22:13:03

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2021-02-08T16:13:01', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '06406f8d-9491-4caf-94f4-871eb82a55bd' User entered '08 Feb 2021 16:13:01'	System	08 Feb 2021 22:13:03
	System	08 Feb 2021 22:13:03

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '08 Feb 2021 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '12 Feb 2021 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2021-02-15T08:37:48', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '0d7a7599-d51e-4e93-90dd-b330bcfb78d8'	System	15 Feb 2021 14:37:55
User entered 'No (N)'	System	15 Feb 2021 14:37:55

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

Have you been exposed to someone with 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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2021-02-15T08:37:50', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '0d7a7599-d51e-4e93-90dd-b330bcfb78d8'	System	15 Feb 2021 14:37:55
User entered 'No (N)'	System	15 Feb 2021 14:37:55

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2021-02-15T08:37:52', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '0d7a7599-d51e-4e93-90dd-b330bcfb78d8'	System	15 Feb 2021 14:37:55
User entered '15 Feb 2021 08:37:52'	System	15 Feb 2021 14:37:55

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '15 Feb 2021 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '19 Feb 2021 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2021-02-22T00:53:11', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '3aec90c6-4d06-4ba0-8a1f-8a6ada55285f' User entered 'No (N)'	System	22 Feb 2021 06:53:22

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

Have you been exposed to someone with 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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2021-02-22T00:53:16', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '3aec90c6-4d06-4ba0-8a1f-8a6ada55285f' User entered 'No (N)'	System	22 Feb 2021 06:53:22

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2021-02-22T00:53:19', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '3aec90c6-4d06-4ba0-8a1f-8a6ada55285f' User entered '22 Feb 2021 00:53:19'	System	22 Feb 2021 06:53:22
	System	22 Feb 2021 06:53:22

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '22 Feb 2021 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '26 Feb 2021 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2021-03-01T07:12:32', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'ae6da863-c8b6-4e10-b504-99c0ab2b4240'	System	01 Mar 2021 13:12:40
User entered 'No (N)'	System	01 Mar 2021 13:12:40

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

Have you been exposed to someone with 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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2021-03-01T07:12:35', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'ae6da863-c8b6-4e10-b504-99c0ab2b4240'	System	01 Mar 2021 13:12:40
User entered 'No (N)'	System	01 Mar 2021 13:12:40

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2021-03-01T07:12:37', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'ae6da863-c8b6-4e10-b504-99c0ab2b4240'	System	01 Mar 2021 13:12:40
User entered '01 Mar 2021 07:12:37'	System	01 Mar 2021 13:12:40

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '01 Mar 2021 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '05 Mar 2021 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2021-03-08T06:35:22', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'fef3b3f4-a0b0-4f12-abee-fa49bf794472'	System	08 Mar 2021 12:35:32
User entered 'No (N)'	System	08 Mar 2021 12:35:32

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

Have you been exposed to someone with 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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2021-03-08T06:35:24', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'fef3b3f4-a0b0-4f12-abee-fa49bf794472'	System	08 Mar 2021 12:35:32
User entered 'No (N)'	System	08 Mar 2021 12:35:32

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2021-03-08T06:35:28', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'fef3b3f4-a0b0-4f12-abee-fa49bf794472' User entered '08 Mar 2021 06:35:28'	System	08 Mar 2021 12:35:32
	System	08 Mar 2021 12:35:32

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '08 Mar 2021 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '12 Mar 2021 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2021-03-15T07:42:12', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '3380a86e-fcd2-4379-a9d6-24c928ed7aa3'	System	15 Mar 2021 12:42:22
User entered 'No (N)'	System	15 Mar 2021 12:42:22

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Have you been exposed to someone with 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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2021-03-15T07:42:15', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '3380a86e-fcd2-4379-a9d6-24c928ed7aa3' User entered 'No (N)'	System	15 Mar 2021 12:42:22
	System	15 Mar 2021 12:42:22

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2021-03-15T07:42:18', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '3380a86e-fcd2-4379-a9d6-24c928ed7aa3' User entered '15 Mar 2021 07:42:18'	System	15 Mar 2021 12:42:22
	System	15 Mar 2021 12:42:22

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '15 Mar 2021 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '19 Mar 2021 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2021-03-22T07:06:16', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'e3bbfa94-57a5-472a-aec5-b1728b802747'	System	22 Mar 2021 12:06:31
User entered 'No (N)'	System	22 Mar 2021 12:06:31

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

Have you been exposed to someone with 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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2021-03-22T07:06:21', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'e3bbfa94-57a5-472a-aec5-b1728b802747'	System	22 Mar 2021 12:06:31
User entered 'No (N)'	System	22 Mar 2021 12:06:31

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2021-03-22T07:06:29', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'e3bbfa94-57a5-472a-aec5-b1728b802747' User entered '22 Mar 2021 07:06:29'	System	22 Mar 2021 12:06:31
	System	22 Mar 2021 12:06:31

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '22 Mar 2021 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '26 Mar 2021 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2021-03-29T20:15:02-05:00', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '003c56d3-8edf-434a-ab81-22a09714f7ee' User entered 'No (N)'	System	06 Apr 2021 15:39:43
	System	06 Apr 2021 15:39:43

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

Have you been exposed to someone with 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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2021-03-29T20:15:04-05:00', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '003c56d3-8edf-434a-ab81-22a09714f7ee' User entered 'No (N)'	System	06 Apr 2021 15:39:43

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2021-03-29T20:15:06-05:00', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '003c56d3-8edf-434a-ab81-22a09714f7ee'	System	06 Apr 2021 15:39:43
User entered '29 Mar 2021 20:15:06'	System	06 Apr 2021 15:39:43

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '29 Mar 2021 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '02 Apr 2021 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2021-04-06T10:39:32-05:00', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '4972f7fa-5d60-43d9-872a-2b58c902edb4' User entered 'No (N)'	System	06 Apr 2021 15:39:44
	System	06 Apr 2021 15:39:44

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

Have you been exposed to someone with 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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2021-04-06T10:39:33-05:00', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '4972f7fa-5d60-43d9-872a-2b58c902edb4'	System	06 Apr 2021 15:39:44
User entered 'No (N)'	System	06 Apr 2021 15:39:44

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2021-04-06T10:39:35-05:00', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '4972f7fa-5d60-43d9-872a-2b58c902edb4'	System	06 Apr 2021 15:39:44
User entered '06 Apr 2021 10:39:35'	System	06 Apr 2021 15:39:44

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '05 Apr 2021 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '09 Apr 2021 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2021-04-12T00:02:14-05:00', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '6e881900-32ce-4fd9-a84c-45da5d0e3de9' User entered 'No (N)'	System	12 Apr 2021 05:02:23
	System	12 Apr 2021 05:02:23

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Have you been exposed to someone with 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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2021-04-12T00:02:16-05:00', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '6e881900-32ce-4fd9-a84c-45da5d0e3de9' User entered 'No (N)'	System	12 Apr 2021 05:02:23
	System	12 Apr 2021 05:02:23

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2021-04-12T00:02:20-05:00', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '6e881900-32ce-4fd9-a84c-45da5d0e3de9' User entered '12 Apr 2021 00:02:20'	System	12 Apr 2021 05:02:23
	System	12 Apr 2021 05:02:23

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '12 Apr 2021 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '16 Apr 2021 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2021-04-20T15:40:38-05:00', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '57e4df75-a38a-4b03-b771-eb884b3c82ef' User entered 'No (N)'	System	20 Apr 2021 20:40:49

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

Have you been exposed to someone with 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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2021-04-20T15:40:43-05:00', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '57e4df75-a38a-4b03-b771-eb884b3c82ef' User entered 'No (N)'	System	20 Apr 2021 20:40:49

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2021-04-20T15:40:47-05:00', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '57e4df75-a38a-4b03-b771-eb884b3c82ef' User entered '20 Apr 2021 15:40:47'	System	20 Apr 2021 20:40:49
	System	20 Apr 2021 20:40:49

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '19 Apr 2021 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '23 Apr 2021 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2021-04-28T12:01:12-05:00', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'aaf2fc28-0067-49ef-9f8d-a07d0e4a0372' User entered 'No (N)'	System	29 Apr 2021 00:12:29

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

Have you been exposed to someone with 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 (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2021-04-28T12:01:16-05:00', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'aaf2fc28-0067-49ef-9f8d-a07d0e4a0372'	System	29 Apr 2021 00:12:29
User entered 'No (N)'	System	29 Apr 2021 00:12:29

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2021-04-28T12:01:25-05:00', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: 'aaf2fc28-0067-49ef-9f8d-a07d0e4a0372'	System	29 Apr 2021 00:12:29
User entered '28 Apr 2021 12:01:25'	System	29 Apr 2021 00:12:29

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '26 Apr 2021 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '30 Apr 2021 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '03 May 2021 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '07 May 2021 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '10 May 2021 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '14 May 2021 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '17 May 2021 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '21 May 2021 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '24 May 2021 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '28 May 2021 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '31 May 2021 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '04 Jun 2021 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '07 Jun 2021 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '11 Jun 2021 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '14 Jun 2021 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '18 Jun 2021 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '21 Jun 2021 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '25 Jun 2021 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '28 Jun 2021 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '02 Jul 2021 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '05 Jul 2021 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '09 Jul 2021 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '12 Jul 2021 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '16 Jul 2021 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '19 Jul 2021 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '23 Jul 2021 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '26 Jul 2021 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '30 Jul 2021 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '02 Aug 2021 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '06 Aug 2021 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '09 Aug 2021 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '13 Aug 2021 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '16 Aug 2021 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '20 Aug 2021 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '23 Aug 2021 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '27 Aug 2021 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '30 Aug 2021 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '03 Sep 2021 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '06 Sep 2021 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '10 Sep 2021 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '13 Sep 2021 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '17 Sep 2021 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '20 Sep 2021 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '24 Sep 2021 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '27 Sep 2021 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '01 Oct 2021 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '04 Oct 2021 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '08 Oct 2021 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '11 Oct 2021 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '15 Oct 2021 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '18 Oct 2021 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '22 Oct 2021 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '25 Oct 2021 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '29 Oct 2021 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '01 Nov 2021 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '05 Nov 2021 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '08 Nov 2021 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '12 Nov 2021 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '15 Nov 2021 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '19 Nov 2021 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '22 Nov 2021 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '26 Nov 2021 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '29 Nov 2021 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '03 Dec 2021 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '06 Dec 2021 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '10 Dec 2021 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '13 Dec 2021 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '17 Dec 2021 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '20 Dec 2021 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '24 Dec 2021 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '27 Dec 2021 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '31 Dec 2021 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '03 Jan 2022 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '07 Jan 2022 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '10 Jan 2022 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '14 Jan 2022 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '17 Jan 2022 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '21 Jan 2022 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '24 Jan 2022 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '28 Jan 2022 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '31 Jan 2022 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '04 Feb 2022 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '07 Feb 2022 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '11 Feb 2022 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '14 Feb 2022 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '18 Feb 2022 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '21 Feb 2022 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '25 Feb 2022 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '28 Feb 2022 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '04 Mar 2022 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '07 Mar 2022 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '11 Mar 2022 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '14 Mar 2022 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '18 Mar 2022 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '21 Mar 2022 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '25 Mar 2022 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '28 Mar 2022 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '01 Apr 2022 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '04 Apr 2022 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '08 Apr 2022 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '11 Apr 2022 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '15 Apr 2022 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '18 Apr 2022 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '22 Apr 2022 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '25 Apr 2022 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '29 Apr 2022 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '02 May 2022 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '06 May 2022 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '09 May 2022 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '13 May 2022 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '16 May 2022 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '20 May 2022 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '23 May 2022 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '27 May 2022 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '30 May 2022 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '03 Jun 2022 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '06 Jun 2022 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '10 Jun 2022 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '13 Jun 2022 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '17 Jun 2022 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '20 Jun 2022 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '24 Jun 2022 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '27 Jun 2022 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '01 Jul 2022 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '04 Jul 2022 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '08 Jul 2022 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '11 Jul 2022 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '15 Jul 2022 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '18 Jul 2022 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '22 Jul 2022 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '25 Jul 2022 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '29 Jul 2022 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '01 Aug 2022 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '05 Aug 2022 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '08 Aug 2022 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '12 Aug 2022 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '15 Aug 2022 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '19 Aug 2022 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '22 Aug 2022 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '26 Aug 2022 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '29 Aug 2022 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '02 Sep 2022 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '05 Sep 2022 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '09 Sep 2022 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '12 Sep 2022 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '16 Sep 2022 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '19 Sep 2022 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '23 Sep 2022 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '26 Sep 2022 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '30 Sep 2022 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '03 Oct 2022 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '07 Oct 2022 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '10 Oct 2022 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '14 Oct 2022 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '17 Oct 2022 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '21 Oct 2022 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '24 Oct 2022 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '28 Oct 2022 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '31 Oct 2022 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '04 Nov 2022 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '07 Nov 2022 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '11 Nov 2022 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '14 Nov 2022 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '18 Nov 2022 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '21 Nov 2022 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '25 Nov 2022 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '28 Nov 2022 00:01'	System	20 Nov 2020 10:57:51

US3342286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:36:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:57:51
Amendment Manager: User entered '02 Dec 2022 23:59'	System	20 Nov 2020 10:57:51

US3342286

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:36:11

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)	25 Apr 2021 02:16:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2021-03-01T07:12:46', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '1522312f-cb38-4ea7-afbb-28ac627773e7'	System	01 Mar 2021 13:12:55
User entered 'No (N)'	System	01 Mar 2021 13:12:55

US3342286

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:36:11

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:16:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (99F4BF99-FEDC-4B6C-9B0A-A0C39BBBC682)', Time: '2021-03-01T07:12:51', User OID: 'PatientReportedOutcome (US3342286)', ODM File OID: '1522312f-cb38-4ea7-afbb-28ac627773e7' User entered '01 Mar 2021 07:12:51'	System	01 Mar 2021 13:12:55
	System	01 Mar 2021 13:12:55

US3342286

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Dec 2020 20:04:24

US3342286

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered '18 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Dec 2020 20:04:24

US3342286

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	18 Dec 2020 20:04:24

US3342286

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 20:04:24

US3342286

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Dec 2020 20:04:29

US3342286

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:03:48
User entered '1'	System	18 Dec 2020 20:04:29

US3342286

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:40:36
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:06
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	21 Jan 2021 20:21:38

US3342286

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:40:36
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:06
User entered '21 Jan 2021'	Ethan Shotton (b) (4)	21 Jan 2021 20:21:38

US3342286

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:40:36
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:06
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4)	21 Jan 2021 20:21:38

US3342286

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:40:36
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:06
User entered empty.	Ethan Shotton (b) (4)	21 Jan 2021 20:21:38

US3342286

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:40:36
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:06
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	21 Jan 2021 20:21:41

US3342286

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:40:36
User entered '1'	System	21 Jan 2021 20:21:41

US3342286

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:40:36
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:39:06

US3342286

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:40:36
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered '24 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:39:06

US3342286

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:40:36
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:39:06

US3342286

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:40:36
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 16:39:06

US3342286

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:40:36
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 22:59:23

US3342286

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:40:36
User entered '1'	System	24 Feb 2021 22:59:23

US3342286

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:40:36
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:24:35

US3342286

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:40:36
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered '22 Mar 2021'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:24:35

US3342286

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:40:36
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:24:35

US3342286

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:36:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:40:36
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:24:35

US3342286

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:40:36
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:17:43

US3342286

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:36:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:40:36
User entered '1'	System	22 Mar 2021 19:17:43

US3342286

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

Form: Unblinding

Generated On: 11 Aug 2021 22:36:11

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:55:35
User entered '25 Jan 2021'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 18:13:24

US3342286

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

Form: Unblinding

Generated On: 11 Aug 2021 22:36:11

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:55:35
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 18:13:24

US3342286

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

Form: Unblinding

Generated On: 11 Aug 2021 22:36:11

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:55:35
User closed query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' (Site from System).	(b) (4)	31 Mar 2021 18:13:43
Query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' answered by data change (Site from System).	System	31 Mar 2021 18:13:43
User opened query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' (Site from System).	System	31 Mar 2021 18:13:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Mar 2021 18:13:24

US3342286

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

Form: Unblinding

Generated On: 11 Aug 2021 22:36:11

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:55:35
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 18:13:24

US3342286

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

Form: Unblinding

Generated On: 11 Aug 2021 22:36:11

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:55:35
User entered '25 Jan 2021' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	31 Mar 2021 18:13:43
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 18:13:24

US3342286

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

Form: Unblinding

Generated On: 11 Aug 2021 22:36:11

[Participant randomization assignment](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:55:35
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 18:13:24

US3342286

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

Form: Unblinding

Generated On: 11 Aug 2021 22:36:11

[Actual Dose 1](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:55:35
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 18:13:24

US3342286

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

Form: Unblinding

Generated On: 11 Aug 2021 22:36:11

[Actual Dose 2](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:55:35
User entered 'Not Administered (NA)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 18:13:24

US3342286

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

Form: Unblinding

Generated On: 11 Aug 2021 22:36:11

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:55:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 18:13:24

US3342286

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

Form: Unblinding

Generated On: 11 Aug 2021 22:36:11

[Placebo Only Flag](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 18:13:24

US3342286

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

Form: Unblinding

Generated On: 11 Aug 2021 22:36:11

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 18:13:24

US3342286

Folder: **Unscheduled 19 Mar 2021**

Form: **Unscheduled Visit Assessment**

Generated On: **11 Aug 2021 22:36:11**

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered '19 Mar 2021'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:48:00

US3342286

Folder: Unscheduled 19 Mar 2021

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:36:11

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered 'I'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:48:00

US3342286

Folder: Unscheduled 19 Mar 2021

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:36:11

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered 'I'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:48:00

US3342286

Folder: **Unscheduled 19 Mar 2021**

Form: **Unscheduled Visit Assessment**

Generated On: **11 Aug 2021 22:36:11**

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:48:00

US3342286

Folder: **Unscheduled 19 Mar 2021**

Form: **Unscheduled Visit Assessment**

Generated On: **11 Aug 2021 22:36:11**

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:06
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:48:00

US3342286

Folder: Unscheduled 19 Mar 2021

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:48:57

US3342286

Folder: Unscheduled 19 Mar 2021

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered '19 Mar 2021'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:48:57

US3342286

Folder: Unscheduled 19 Mar 2021

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered '10:07'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:48:57

US3342286

Folder: Unscheduled 19 Mar 2021

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:12
User entered '19 Mar 2021 10:07'	System	19 Mar 2021 19:48:57

US3342286

Folder: Unscheduled 19 Mar 2021

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered '97.9' F	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:48:57

US3342286

Folder: Unscheduled 19 Mar 2021

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:48:57

US3342286

Folder: Unscheduled 19 Mar 2021

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:48:57

US3342286

Folder: Unscheduled 19 Mar 2021

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered '71'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:48:57

US3342286

Folder: Unscheduled 19 Mar 2021

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:12
User entered 'bpm'	System	19 Mar 2021 19:48:57

US3342286

Folder: Unscheduled 19 Mar 2021

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered '14'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:48:57

US3342286

Folder: Unscheduled 19 Mar 2021

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:12
User entered 'breaths/min'	System	19 Mar 2021 19:48:57

US3342286

Folder: Unscheduled 19 Mar 2021

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered '181'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:48:57

US3342286

Folder: Unscheduled 19 Mar 2021

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:12
User entered 'mmHg'	System	19 Mar 2021 19:48:57

US3342286

Folder: Unscheduled 19 Mar 2021

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:12
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	22 Mar 2021 13:07:54
User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	22 Mar 2021 13:07:51
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Pt's BP considered CS per investigator discretion. Pt. prompted to follow up with PCP ASAP. Pt's condition will be followed closely by study site. ' (Site from System).	(b) (4), (b) (6)	19 Mar 2021 19:51:46
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Pt's BP considered CS per investigator discretion. Pt. prompted to follow up with PCP ASAP. Pt's condition will be followed closely by study site. ' (Site from System).	(b) (4), (b) (6)	19 Mar 2021 19:51:41
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		19 Mar 2021 19:48:57
User opened query 'Diastolic Blood Pressure reported System is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		19 Mar 2021 19:48:57
User entered '117'	(b) (4), (b) (6)	19 Mar 2021 19:48:57

US3342286

Folder: Unscheduled 19 Mar 2021

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:12
User entered 'mmHg'	System	19 Mar 2021 19:48:57

US3342286

Folder: Unscheduled 19 Mar 2021

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 23:52:12

US3342286

Folder: Unscheduled 19 Mar 2021

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 23:52:12

US3342286

Folder: Unscheduled 19 Mar 2021

Form: Physical Examination

Generated On: 11 Aug 2021 22:36:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:16
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:51:55

US3342286

Folder: Unscheduled 19 Mar 2021

Form: Physical Examination

Generated On: 11 Aug 2021 22:36:11

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:52:16
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered '19 Mar 2021'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:51:55

US3342286

Folder: Unscheduled 21 Oct 2020

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:36:11

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:59:22
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered '21 Oct 2020'	(b) (4) John Luna (b) (4)	26 Oct 2020 20:42:13

US3342286

Folder: Unscheduled 21 Oct 2020

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:36:11

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:59:22
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered 'I'	John Luna (b) (4)	26 Oct 2020 20:42:13

US3342286

Folder: Unscheduled 21 Oct 2020

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:36:11

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:59:22
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered 'I'	John Luna (b) (4)	26 Oct 2020 20:42:13

US3342286

Folder: **Unscheduled 21 Oct 2020**

Form: **Unscheduled Visit Assessment**

Generated On: **11 Aug 2021 22:36:11**

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:59:22
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered '0'	John Luna (b) (4)	26 Oct 2020 20:42:13

US3342286

Folder: **Unscheduled 21 Oct 2020**

Form: **Unscheduled Visit Assessment**

Generated On: **11 Aug 2021 22:36:11**

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:59:22
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered '0'	(b) (4) John Luna (b) (4)	26 Oct 2020 20:42:13

US3342286

Folder: Unscheduled 21 Oct 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:59:28
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered 'Yes (Y)'	John Luna (b) (4)	26 Oct 2020 20:42:49

US3342286

Folder: Unscheduled 21 Oct 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:59:28
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered '21 Oct 2020'	(b) (4) John Luna (b) (4)	26 Oct 2020 20:42:49

US3342286

Folder: Unscheduled 21 Oct 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:59:28
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered '13:27'	John Luna (b) (4)	26 Oct 2020 20:42:49

US3342286

Folder: Unscheduled 21 Oct 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:59:28
User entered '21 Oct 2020 13:27'	System	26 Oct 2020 20:42:49

US3342286

Folder: Unscheduled 21 Oct 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:59:28
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered '98.3' F	John Luna (b) (4)	26 Oct 2020 20:42:49

US3342286

Folder: Unscheduled 21 Oct 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:59:28
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered 'Oral (Oral)'	John Luna (b) (4)	26 Oct 2020 20:42:49

US3342286

Folder: Unscheduled 21 Oct 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:59:28
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered empty.	(b) (4) John Luna (b) (4)	26 Oct 2020 20:42:49

US3342286

Folder: Unscheduled 21 Oct 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:59:28
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered '63'	John Luna (b) (4)	26 Oct 2020 20:42:49

US3342286

Folder: Unscheduled 21 Oct 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:59:28
User entered 'bpm'	System	26 Oct 2020 20:42:49

US3342286

Folder: Unscheduled 21 Oct 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:59:28
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered '14'	John Luna (b) (4)	26 Oct 2020 20:42:49

US3342286

Folder: Unscheduled 21 Oct 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:59:28
User entered 'breaths/min'	System	26 Oct 2020 20:42:49

US3342286

Folder: Unscheduled 21 Oct 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:59:28
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered '165'	John Luna (b) (4)	26 Oct 2020 20:42:49

US3342286

Folder: Unscheduled 21 Oct 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:59:28
User entered 'mmHg'	System	26 Oct 2020 20:42:49

US3342286

Folder: Unscheduled 21 Oct 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:59:28
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:05:39
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Subject to follow up with PCP per investigator.' (Site from System).	John Luna (b) (4)	26 Oct 2020 20:43:36
User opened query 'Diastolic Blood Pressure reported System is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		26 Oct 2020 20:42:49
User entered '109'	John Luna (b) (4)	26 Oct 2020 20:42:49

US3342286

Folder: Unscheduled 21 Oct 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:59:28
User entered 'mmHg'	System	26 Oct 2020 20:42:49

US3342286

Folder: Unscheduled 21 Oct 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:59:28

US3342286

Folder: Unscheduled 21 Oct 2020

Form: Vital Signs

Generated On: 11 Aug 2021 22:36:11

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:59:28

US3342286

Folder: Unscheduled 21 Oct 2020

Form: Physical Examination

Generated On: 11 Aug 2021 22:36:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:59:36
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered 'Yes (Y)'	John Luna (b) (4)	26 Oct 2020 20:43:43

US3342286

Folder: Unscheduled 21 Oct 2020

Form: Physical Examination

Generated On: 11 Aug 2021 22:36:11

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:59:36
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:14
User entered '21 Oct 2020'	(b) (4) John Luna (b) (4)	26 Oct 2020 20:43:43

US3342286

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:36:11

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:10
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:42:34
User entered 'Yes (Y)'	John Luna (b) (4)	22 Oct 2020 19:20:29

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:11

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:42:34
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension NOS - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	22 Oct 2020 21:27:19
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 21:27:19
Data point term sent to Coder	System	22 Oct 2020 19:22:48
User entered 'Hypertension (Unspecified)'	John Luna (b) (4)	22 Oct 2020 19:21:48

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:11

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:42:34
User entered 'No (N)'	(b) (4) John Luna (b) (4)	22 Oct 2020 19:21:48

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:11

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:42:34
User entered 'No (N)'	(b) (4) John Luna (b) (4)	22 Oct 2020 19:21:48

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:42:34
User entered 'No (N)'	(b) (4) John Luna (b) (4)	22 Oct 2020 19:21:48

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:11

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:42:34
User entered '21 Oct 2020'	(b) (4) John Luna (b) (4)	22 Oct 2020 19:21:48

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:11

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:42:34
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)	22 Oct 2020 19:22:12
User entered empty; reason for change Data Entry Error	John Luna (b) (4)	22 Oct 2020 19:22:12
Query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' answered with 'data corrected' (Site from System).	John Luna (b) (4)	22 Oct 2020 19:22:05
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	22 Oct 2020 19:21:48
User entered '13:27'	John Luna (b) (4)	22 Oct 2020 19:21:48

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:11

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 19:22:12
User entered '21 Oct 2020 13:27'	System	22 Oct 2020 19:21:48

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:42:34
User entered 'Yes (Y)'	(b) (4) John Luna (b) (4)	22 Oct 2020 19:21:48

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:11

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:42:34
User entered empty.	(b) (4) John Luna (b) (4)	22 Oct 2020 19:21:48

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:11

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:42:34
User entered empty.	(b) (4) John Luna (b) (4)	22 Oct 2020 19:21:48

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:11

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 19:21:48

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:11

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:42:34
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) John Luna (b) (4)	22 Oct 2020 19:21:48

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:11

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:42:34
	(b) (4)	
User entered 'No (N)'	John Luna (b) (4)	22 Oct 2020 19:21:48

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:42:34
User entered '0'	(b) (4) John Luna (b) (4)	22 Oct 2020 19:21:48

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:42:34
User entered '0'	(b) (4) John Luna (b) (4)	22 Oct 2020 19:21:48

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:42:34
User entered '0'	(b) (4) John Luna (b) (4)	22 Oct 2020 19:21:48

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:11

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:42:34
User entered empty.	(b) (4) John Luna (b) (4)	22 Oct 2020 19:21:48

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:11

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:42:34
User entered empty.	(b) (4) John Luna (b) (4)	22 Oct 2020 19:21:48

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:11

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:42:34
User entered empty.	(b) (4) John Luna (b) (4)	22 Oct 2020 19:21:48

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:11

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:42:34
User entered empty.	(b) (4) John Luna (b) (4)	22 Oct 2020 19:21:48

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:42:34
User entered '0'	(b) (4) John Luna (b) (4)	22 Oct 2020 19:21:48

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:42:34
User entered '0'	(b) (4) John Luna (b) (4)	22 Oct 2020 19:21:48

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:42:34
User entered '0'	(b) (4) John Luna (b) (4)	22 Oct 2020 19:21:48

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:11

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:42:34
User entered 'Not Related (NOT RELATED)'	(b) (4) John Luna (b) (4)	22 Oct 2020 19:21:48

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:11

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:42:34
User entered 'Not Related (NOT RELATED)'	(b) (4) John Luna (b) (4)	22 Oct 2020 19:21:48

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:11

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:42:34
User closed query 'Per CDM: Please consider updating this field to "Investigational product withdrawn". Thank you!' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Jan 2021 07:08:51
Query 'Per CDM: Please consider updating this field to "Investigational product withdrawn". Thank you!' answered with 'Action Taken Updated' (Site from DM).	Ethan Shotton (b) (4) (b) (4)	21 Jan 2021 20:21:30
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Ethan Shotton (b) (4) (b) (4)	21 Jan 2021 20:21:23
User opened query 'Per CDM: Please consider updating this field to "Investigational product withdrawn". Thank you!' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 10:11:06
User entered 'Dose Delayed (DOSE DELAYED)'	John Luna (b) (4)	22 Oct 2020 19:21:48

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:11

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:42:34
User entered 'I'	(b) (4) John Luna (b) (4)	22 Oct 2020 19:21:48

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:11

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:42:34
User entered '0'	(b) (4) John Luna (b) (4)	22 Oct 2020 19:21:48

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:11

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:42:34
User entered '0'	(b) (4) John Luna (b) (4)	22 Oct 2020 19:21:48

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:11

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:42:34
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) John Luna (b) (4)	22 Oct 2020 19:21:48

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:11

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:42:34
User entered empty.	(b) (4) John Luna (b) (4)	22 Oct 2020 19:21:48

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:11

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:42:34
User entered 'CALLED PT TO F/U ON ELEVATED BP. PT DID NOT ANSWER, BUT PI LEFT DETAILED VOICEMAIL. REMINDED PT OF VISIT AND RECOMMENDATION HE SEE A PCP RE: BP. THIS RECOMMENDATION WAS REITERATED BY DR. PICKRELL AT A SUBSEQUENT VISIT. PI OFFERED THAT WE HAVE A LIST OF ACCESSIBLE CLINICS IN CASE PT IN UNABLE TO SEE HIS WIFE'S MD AS HE HOPED. PI SPECIFICALLY MENTIONED LONE STAR CIRCLE OF CARE, WHICH HAS LOCATIONS IN TRAVIS AND WILLIAMSON COUNTIES. LIST OBTAINED FROM CITY OF AUSTIN WEBSITE, WHICH PI REFERENCED TO HIM. (b) (6) 02NOV2020.	(b) (4) Darrell O'Brien (b) (4)	20 Nov 2020 18:21:41

UPDATE: AT PT VISIT 3 (20NOV20230) PT WAS ASKED IF HE F/U WITH PCP/MEDICAL PROVIDER REGARDING ELEVATED BP. PT STATED THAT HE HAD NOT FOLLOWED UP WITH ANYONE IRT THE ELEVATED BP. PT STILL INTENDS ON SEEING MEDICAL PROVIDER (SPECIFICALLY STATING "LONE STAR") AFTER THANKSGIVING. HE WAS INFORMED THAT HE WOULD BE ABLE TO HAVE AN APPOINTMENT AT THAT TIME. PT NEEDS TO CALL CLINIC IN ORDER TO SCHEDULED APPOINTMENT AFTER THANKSGIVING. WILL F/U WITH PT AND MONITOR FOR ADDITIONAL INFORMATION. due to patient's elevated bp at visit 3, sx directed physical conducted focused on cardiovascular assessment. DAO 20NOV2020.' reason for change: New Information

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:11

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Called pt to f/u on elevated BP. Pt did not answer, but PI left detailed voicemail. Reminded pt of visit and recommendation he see a PCP re: BP. This recommendation was reiterated by Dr. Pickrell at a subsequent visit. PI offered that we have a list of accessible clinics in case pt in unable to see his wife's MD as he hoped. PI specifically mentioned lone star circle of care, which has locations in Travis and Williamson Counties. List obtained from city of austin website, which PI referenced to him. (b) (6) (b) (6) 02NOV2020. Update: at pt Visit 3 (20NOV20230) pt was asked if he f/u with pcp/medical provider regarding elevated bp. Pt stated that he had not followed up with anyone irt the elevated bp. Pt still intends on seeing medical provider (specifically stating "lone star") after Thanksgiving. He was informed that he would be able to have an appointment at that time. Pt needs to call clinic in order to scheduled appointment after Thanksgiving. Will f/u with pt and monitor for additional information. DAO 20NOV2020.' reason for change: Data Entry Error User entered empty.	Darrell O'Brien (b) (4) (b) (4)	20 Nov 2020 18:01:35
	John Luna (b) (4)	22 Oct 2020 19:21:48

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:11

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	22 Oct 2020 19:21:48

US3342286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:36:11

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	22 Oct 2020 19:21:48

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:36:11

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:50:10
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:36:17
User entered 'Yes (Y)'	Darrell O'Brien (b) (4)	26 Sep 2020 17:04:21

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:36:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:36:17
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	26 Sep 2020 17:06:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Sep 2020 17:06:45
Data point term sent to Coder	System	26 Sep 2020 17:06:04
User entered 'Diphenhydramine'	Darrell O'Brien (b) (4) (b) (4)	26 Sep 2020 17:05:04

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:36:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:36:17
	(b) (4)	
User entered 'No (N)'	Darrell O'Brien (b) (4)	26 Sep 2020 17:05:04
	(b) (4)	

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:36:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:36:17
	(b) (4)	
User entered 'Seasonal Allergies'	Darrell O'Brien (b) (4)	26 Sep 2020 17:05:04
	(b) (4)	

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:36:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:36:17
	(b) (4)	
User entered '50'	Darrell O'Brien (b) (4)	26 Sep 2020 17:05:04
	(b) (4)	

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:36:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:36:17
	(b) (4)	
User entered 'mg (mg)'	Darrell O'Brien (b) (4)	26 Sep 2020 17:05:04
	(b) (4)	

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:36:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:36:17
	(b) (4)	
User entered empty.	Darrell O'Brien (b) (4)	26 Sep 2020 17:05:04
	(b) (4)	

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:36:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:36:17
	(b) (4)	
User entered 'as needed (PRN)'	Darrell O'Brien (b) (4)	26 Sep 2020 17:05:04
	(b) (4)	

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:36:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:36:17
	(b) (4)	
User entered empty.	Darrell O'Brien (b) (4)	26 Sep 2020 17:05:04
	(b) (4)	

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:36:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:36:17
User entered 'Oral (ORAL)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	26 Sep 2020 17:05:04

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:36:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:36:17
	(b) (4)	
User entered empty.	Darrell O'Brien (b) (4)	26 Sep 2020 17:05:04
	(b) (4)	

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:36:17
	(b) (4)	
User entered 'un UNK 2020'	Darrell O'Brien (b) (4)	26 Sep 2020 17:05:04
	(b) (4)	

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:36:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:36:17
User entered '0'	(b) (4) Darrell O'Brien (b) (4)	26 Sep 2020 17:05:04
	(b) (4)	

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:36:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:36:17
	(b) (4)	
User entered 'Yes (Y)'	Darrell O'Brien (b) (4)	26 Sep 2020 17:05:04
	(b) (4)	

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:36:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:36:17
User entered empty.	(b) (4) Darrell O'Brien (b) (4)	26 Sep 2020 17:05:04
	(b) (4)	

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:36:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:36:17
User entered 'No (N)'	(b) (4) Darrell O'Brien (b) (4)	26 Sep 2020 17:05:04

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:36:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Sep 2020 17:05:04

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:36:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Sep 2020 17:05:04

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:36:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Sep 2020 17:05:04

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:36:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:36:17
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.	(b) (4) Coder Import (b) (4) (b) (4)	26 Sep 2020 17:06:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Sep 2020 17:06:45
Data point term sent to Coder	System	26 Sep 2020 17:06:04
User entered 'Ibuprofen'	Darrell O'Brien (b) (4) (b) (4)	26 Sep 2020 17:05:37

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:36:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:36:17
	(b) (4)	
User entered 'No (N)'	Darrell O'Brien (b) (4)	26 Sep 2020 17:05:37
	(b) (4)	

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:36:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:36:17
User entered 'Generalized Pain'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	26 Sep 2020 17:05:37

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:36:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:36:17
	(b) (4)	
User entered '200'	Darrell O'Brien (b) (4)	26 Sep 2020 17:05:37
	(b) (4)	

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:36:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:36:17
	(b) (4)	
User entered 'mg (mg)'	Darrell O'Brien (b) (4)	26 Sep 2020 17:05:37
	(b) (4)	

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:36:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:36:17
	(b) (4)	
User entered empty.	Darrell O'Brien (b) (4)	26 Sep 2020 17:05:37
	(b) (4)	

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:36:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:36:17
	(b) (4)	
User entered 'as needed (PRN)'	Darrell O'Brien (b) (4)	26 Sep 2020 17:05:37
	(b) (4)	

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:36:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:36:17
	(b) (4)	
User entered empty.	Darrell O'Brien (b) (4)	26 Sep 2020 17:05:37
	(b) (4)	

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:36:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:36:17
	(b) (4)	
User entered 'Oral (ORAL)'	Darrell O'Brien (b) (4)	26 Sep 2020 17:05:37
	(b) (4)	

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:36:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:36:17
	(b) (4)	
User entered empty.	Darrell O'Brien (b) (4)	26 Sep 2020 17:05:37
	(b) (4)	

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:36:11

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

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:36:17
	(b) (4)	
User entered 'un UNK 2000'	Darrell O'Brien (b) (4)	26 Sep 2020 17:05:37
	(b) (4)	

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:36:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:36:17
User entered '0'	(b) (4) Darrell O'Brien (b) (4)	26 Sep 2020 17:05:37
	(b) (4)	

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:36:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:36:17
	(b) (4)	
User entered 'Yes (Y)'	Darrell O'Brien (b) (4)	26 Sep 2020 17:05:37
	(b) (4)	

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:36:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:36:17
	(b) (4)	
User entered empty.	Darrell O'Brien (b) (4)	26 Sep 2020 17:05:37
	(b) (4)	

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:36:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:36:17
	(b) (4)	
User entered 'No (N)'	Darrell O'Brien (b) (4)	26 Sep 2020 17:05:37
	(b) (4)	

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:36:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Sep 2020 17:05:37

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:36:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Sep 2020 17:05:37

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:36:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Sep 2020 17:05:37

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:36:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:58
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 13:31:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 13:31:37
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	22 Mar 2021 13:36:17
Data point term sent to Coder User entered 'Lisinopril'	System (b) (4), (b) (6)	19 Mar 2021 19:54:00 19 Mar 2021 19:53:10

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:36:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:58
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:36:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:53:10

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:36:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:58
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:36:17
User entered 'Hypertension Unspecified'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:53:10

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:36:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:58
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:36:17
User entered '10'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:53:10

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:36:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:58
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:36:17
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:53:10

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:36:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:58
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:36:17
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:53:10

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:36:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:58
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:36:17
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:53:10

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:36:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:58
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:36:17
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:53:10

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:36:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:58
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:36:17
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:53:10

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:36:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:58
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:36:17
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:53:10

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:36:11

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:58
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:36:17
User entered '25 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:53:10

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:36:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:58
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:36:17
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:53:10

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:36:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:58
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:36:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:53:10

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:36:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:58
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:36:17
User entered '19 Mar 2021'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:53:10

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:36:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:58
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:36:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:53:10

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:36:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:58
User entered '1'	System	19 Mar 2021 19:53:10

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:36:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:58
User entered '1'	System	19 Mar 2021 19:53:10

US3342286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:36:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:57:58
User entered '804 (804)'	System	19 Mar 2021 19:53:10

US3342286

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:36:11

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	22 Mar 2021 13:36:17
	(b) (4)	
User entered 'No (N)'	Ethan Shotton (b) (4)	04 Mar 2021 23:39:49
	(b) (4)	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:36:11

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:46:53
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:06
User entered '21 Oct 2020'	Darrell O'Brien (b) (4)	20 Nov 2020 20:50:15

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:36:11

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:46:53
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:06
User entered 'AE (specify) (ADVERSE EVENT)'	Darrell O'Brien (b) (4)	20 Nov 2020 20:50:15

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:36:11

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 12:46:53
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 16:36:06
User closed query 'Per CDM: please record the record line number per CCGs (i.e. AE#1 or SAE#1, etc.) and remove the details' (Site from DM).	(b) (4)	
Query 'Per CDM: please record the record line number per CCGs (i.e. AE#1 or SAE#1, etc.) and remove the details' answered with 'EDC has been updated.' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 09:13:00
User entered 'AE #1' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4)	25 Nov 2020 20:17:30
User opened query 'Per CDM: please record the record line number per CCGs (i.e. AE#1 or SAE#1, etc.) and remove the details' (Site from DM).	(b) (4)	
User entered 'AE: Hypertension, unspecified.'	Olivia Hapanowicz (b) (4)	25 Nov 2020 20:17:21
	(b) (4), (b) (6)	23 Nov 2020 01:46:16
	Darrell O'Brien (b) (4)	20 Nov 2020 20:50:15
	(b) (4)	