

US3352349 (Prod: Research Centers of America - ERG)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:15:59

All time stamps listed in this document are displayed in GMT

US3352349

Form: Participant Creation

Data signed: (b) (4) 28 Apr 2021 15:02:00

Generated On: 09 Jun 2021 17:15:59

Participant ID

US3352349

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

US3352349

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 15:02:01

Generated On: 09 Jun 2021 17:15:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 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) 28 Apr 2021 15:02:00

Generated On: 09 Jun 2021 17:15:59

Date of Birth (MMM yyyy)	(b) (6) 1969
Age	51
Age Units	YEARS
Age (Derived)	51
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) 28 Apr 2021 15:02:00

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Date of Informed Consent (*dd MMM yyyy*) 10 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

US3352349

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 28 Apr 2021 15:02:00

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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) 28 Apr 2021 15:02:00

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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) 28 Apr 2021 15:02:00

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Condition	ALCOHOL CONSUMPTION
Start date (dd MMM yyyy)	UN UNK 1986
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 1986
Start Year (derived)	1986
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 28 Apr 2021 15:02:00

Generated On: 09 Jun 2021 17:15:59

Condition	OBESITY
Start date (dd MMM yyyy)	UN MAY 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)	MAY 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 15:04:24

Generated On: 09 Jun 2021 17:15:59

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	10 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	14:04 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 14:04
Height (<i>xxx.x</i>)	168 cm
Weight (<i>xxx.x</i>)	89.8 kg
BMI (<i>xxx.x</i>)	31.81689 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 15:02:00

Generated On: 09 Jun 2021 17:15:59

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 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) 28 Apr 2021 15:02:01

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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

FREQUENT GROUP BIKE RIDING

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) 28 Apr 2021 15:02:01

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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)	True
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)	False
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 15:04:25

Generated On: 09 Jun 2021 17:15:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 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) 28 Apr 2021 15:04:25

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What was the date of randomization? (dd MMM yyyy) 10 SEP 2020

What was the participant's randomization number? 113137

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) 28 Apr 2021 15:04:25

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Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Apr 2021 15:04:25

Generated On: 09 Jun 2021 17:15:59

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)	10 SEP 2020
Time of assessment (00:00-23:59)	14:04 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 14:04
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 15:04:25

Generated On: 09 Jun 2021 17:15:59

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)	10 SEP 2020
Time of assessment (00:00-23:59)	15:46 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 15:46
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	93 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 15:04:25

Generated On: 09 Jun 2021 17:15:59

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) 28 Apr 2021 15:04:25

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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) 10 SEP 2020

What was the treatment time? (00:00-23:59) 15:16 (24 HR)

Treatment Date and Time (derived) 10 SEP 2020 15:16

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) 28 Apr 2021 15:04:25

Generated On: 09 Jun 2021 17:15:59

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	10 SEP 2020
Collection time (00:00-23:59)	14:43 (24 HR)
Collection date and time (derived)	10 SEP 2020 14:43

US3352349

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 28 Apr 2021 15:04:25

Generated On: 09 Jun 2021 17:15:59

Collection date (dd MMM yyyy)			10 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:38	10 SEP 2020 14:38
Nasopharyngeal Swab 2	No		

US3352349

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 15:04:25

Generated On: 09 Jun 2021 17:15:59

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: 09 Jun 2021 17:15:59

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

10 SEP 2020 15:48

PC Open Date & Time

10 SEP 2020 15:36

PC Close Date & Time

10 SEP 2020 18:06

US3352349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 19:55

PC Open Date & Time

10 SEP 2020 19:01

PC Close Date & Time

11 SEP 2020 11:59

US3352349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:15:59

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

99.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 19:30

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3352349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 23:45

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3352349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 19:12

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:15:59

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

96.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 23:36

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

16 SEP 2020 03:20

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3352349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

16 SEP 2020 18:28

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

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

10 SEP 2020 15:48

PC Open Date & Time

10 SEP 2020 15:36

PC Close Date & Time

10 SEP 2020 18:06

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

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

10 SEP 2020 19:56

PC Open Date & Time

10 SEP 2020 19:01

PC Close Date & Time

11 SEP 2020 11:59

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:15:59

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

11 SEP 2020 19:31

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:15:59

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

12 SEP 2020 23:45

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:15:59

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

13 SEP 2020 19:12

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:15:59

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

14 SEP 2020 23:36

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 03:20

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:15:59

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

16 SEP 2020 18:28

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

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 ☐

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 15:49
PC Open Date & Time	10 SEP 2020 15:36
PC Close Date & Time	10 SEP 2020 18:06

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

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 ☐

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 19:56
PC Open Date & Time	10 SEP 2020 19:01
PC Close Date & Time	11 SEP 2020 11:59

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:15:59

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 ☒

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:15:59

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 19:32
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:15:59

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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US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:15:59

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 23:46
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:15:59

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

EAB) (1725)

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US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:15:59

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 19:13
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:15:59

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 ☒

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:15:59

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 23:35
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:15:59

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 03:21
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:15:59

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 ☒

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:15:59

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 18:29
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3352349

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 15:02:00

Generated On: 09 Jun 2021 17:15:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3352349

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 15:02:00

Generated On: 09 Jun 2021 17:15:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352349

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 15:02:00

Generated On: 09 Jun 2021 17:15:59

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 26 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3352349

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 15:02:00

Generated On: 09 Jun 2021 17:15:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352349

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 15:02:00

Generated On: 09 Jun 2021 17:15:59

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 2 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3352349

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 15:02:00

Generated On: 09 Jun 2021 17:15:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352349

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 15:04:25

Generated On: 09 Jun 2021 17:15:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 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

US3352349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Apr 2021 15:04:25

Generated On: 09 Jun 2021 17:15:59

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)	8 OCT 2020
Time of assessment (00:00-23:59)	13:16 (24 HR)
Vital Signs Date and Time (derived)	8 OCT 2020 13:16
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	102 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	156 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3352349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 15:04:25

Generated On: 09 Jun 2021 17:15:59

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	8 OCT 2020
Time of assessment (00:00-23:59)	15:10 (24 HR)
Vital Signs Date and Time (derived)	8 OCT 2020 15:10
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	94 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	143 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	97 mmHg
Diastolic Blood Pressure units	MMHG

US3352349

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 15:04:25

Generated On: 09 Jun 2021 17:15:59

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.

US3352349

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 15:04:25

Generated On: 09 Jun 2021 17:15:59

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) 08 OCT 2020

What was the treatment time? (00:00-23:59) 14:40 (24 HR)

Treatment Date and Time (derived) 08 OCT 2020 14:40

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

US3352349

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 15:04:25

Generated On: 09 Jun 2021 17:15:59

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	8 OCT 2020
Collection time (00:00-23:59)	13:37 (24 HR)
Collection date and time (derived)	8 OCT 2020 13:37

US3352349

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 28 Apr 2021 15:04:25

Generated On: 09 Jun 2021 17:15:59

Collection date (dd MMM yyyy)			8 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:33	8 OCT 2020 13:33
Nasopharyngeal Swab 2	No		

US3352349

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 15:04:25

Generated On: 09 Jun 2021 17:15:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

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

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

Yes ☐
No ☐

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

To **TREAT** pain or fever that has already occurred

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

08 OCT 2020 15:00

PC Close Date & Time

08 OCT 2020 17:30

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 96.7 °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	09 OCT 2020 10:15
PC Open Date & Time	08 OCT 2020 18:25
PC Close Date & Time	09 OCT 2020 11:59

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:15:59

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

96.7 °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

09 OCT 2020 22:11

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

11 OCT 2020 09:05

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:15:59

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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 OCT 2020 20:06

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 OCT 2020 21:31

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 OCT 2020 19:50

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 OCT 2020 18:03

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

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 ☐

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

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

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

Yes ☐

No ☐

Please record - **SWELLING/HARDNESS AT INJECTION SITE
(in mm)**

Measure the largest size across any injection site swelling/hardness
with the ruler provided.

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

PC Open Date & Time

08 OCT 2020 15:00

PC Close Date & Time

08 OCT 2020 17:30

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

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

09 OCT 2020 10:15

PC Open Date & Time

08 OCT 2020 18:25

PC Close Date & Time

09 OCT 2020 11:59

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:15:59

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

09 OCT 2020 22:12

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:15:59

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

11 OCT 2020 09:05

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:15:59

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

11 OCT 2020 20:06

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:15:59

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

12 OCT 2020 21:31

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:15:59

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

13 OCT 2020 19:51

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:15:59

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

14 OCT 2020 18:03

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

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 ☐

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

08 OCT 2020 15:00

PC Close Date & Time

08 OCT 2020 17:30

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

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 ☐

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

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

No ☒

Yes ☐

PC Time stamp	09 OCT 2020 10:15
PC Open Date & Time	08 OCT 2020 18:25
PC Close Date & Time	09 OCT 2020 11:59

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:15:59

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 ☒

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:15:59

Yes <input type="checkbox"/>	
PC Time stamp	09 OCT 2020 22:12
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:15:59

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)

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:15:59

Yes <input type="checkbox"/>	
PC Time stamp	11 OCT 2020 09:06
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:15:59

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 ☒

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:15:59

Yes <input type="checkbox"/>	
PC Time stamp	11 OCT 2020 20:07
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:15:59

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

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EAB) (1725)

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:15:59

Yes <input type="checkbox"/>	
PC Time stamp	12 OCT 2020 21:31
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:15:59

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 ☒

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:15:59

Yes <input type="checkbox"/>	
PC Time stamp	13 OCT 2020 19:51
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:15:59

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 ☒

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:15:59

Yes <input type="checkbox"/>	
PC Time stamp	14 OCT 2020 18:04
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3352349

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 15:02:00

Generated On: 09 Jun 2021 17:15:59

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 16 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3352349

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 15:02:00

Generated On: 09 Jun 2021 17:15:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352349

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 15:02:00

Generated On: 09 Jun 2021 17:15:59

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 23 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3352349

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 15:02:00

Generated On: 09 Jun 2021 17:15:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352349

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 15:02:00

Generated On: 09 Jun 2021 17:15:59

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 30 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3352349

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 15:02:00

Generated On: 09 Jun 2021 17:15:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352349

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 15:04:25

Generated On: 09 Jun 2021 17:15:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	3 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

US3352349

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 15:04:25

Generated On: 09 Jun 2021 17:15:59

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	3 NOV 2020
Time of assessment (00:00-23:59)	11:07 (24 HR)
Vital Signs Date and Time (derived)	3 NOV 2020 11:07
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	112 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3352349

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 15:04:25

Generated On: 09 Jun 2021 17:15:59

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.

US3352349

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 15:04:25

Generated On: 09 Jun 2021 17:15:59

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	3 NOV 2020
Collection time (00:00-23:59)	11:27 (24 HR)
Collection date and time (derived)	3 NOV 2020 11:27

US3352349

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 15:04:25

Generated On: 09 Jun 2021 17:15:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352349

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 NOV 2020 00:01:46
Patient Cloud Open Date & Time	10 NOV 2020 00:01
Patient Cloud Close Date & Time	14 NOV 2020 23:59

US3352349

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 NOV 2020 04:00:10

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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	25 NOV 2020 08:39:13
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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	28 NOV 2020 19:16:03
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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	05 DEC 2020 06:52:22
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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	12 DEC 2020 10:18:38
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 DEC 2020 18:16:28

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 DEC 2020 17:45:52
Patient Cloud Open Date & Time	26 DEC 2020 00:01
Patient Cloud Close Date & Time	30 DEC 2020 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 JAN 2021 10:45:09

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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	11 JAN 2021 14:12:52
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 JAN 2021 21:34:21
Patient Cloud Open Date & Time	16 JAN 2021 00:01
Patient Cloud Close Date & Time	20 JAN 2021 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

23 JAN 2021 08:03:51

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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	31 JAN 2021 11:33:57
Patient Cloud Open Date & Time	30 JAN 2021 00:01
Patient Cloud Close Date & Time	03 FEB 2021 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

06 FEB 2021 02:49:06

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

16 FEB 2021 03:57:34

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 FEB 2021 12:13:25

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 173

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

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

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

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

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

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

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

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

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Close Date & Time](#)

03 MAR 2021 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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 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"/>

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Open Date & Time](#)

06 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2021 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 187

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 MAR 2021 00:01
Patient Cloud Close Date & Time	17 MAR 2021 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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 <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"/>

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 MAR 2021 00:01
Patient Cloud Close Date & Time	24 MAR 2021 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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 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"/>

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Open Date & Time](#)

27 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAR 2021 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	True
Chills	False
Cough	True
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" 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 checked="" 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 checked="" type="radio"/>
Date and time of submission	07 APR 2021 22:16:15
Patient Cloud Open Date & Time	03 APR 2021 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	
138 of 1741	

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

07 APR 2021 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

10 APR 2021 09:36:25

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 APR 2021 21:47:06

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 APR 2021 02:25:51

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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 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	03 MAY 2021 08:49:48
Patient Cloud Open Date & Time	01 MAY 2021 00:01
Patient Cloud Close Date & Time	05 MAY 2021 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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="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"/>

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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"/>

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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="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"/>

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	05 JUN 2021 00:01
Patient Cloud Close Date & Time	09 JUN 2021 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 JUN 2021 00:01
Patient Cloud Close Date & Time	16 JUN 2021 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 285

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	03 JUL 2021 00:01
Patient Cloud Close Date & Time	07 JUL 2021 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Open Date & Time](#)

10 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 JUL 2021 00:01
Patient Cloud Close Date & Time	21 JUL 2021 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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"/>

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 334

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

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

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

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

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

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

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

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

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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="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"/>

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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="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"/>

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 SEP 2021 00:01
Patient Cloud Close Date & Time	15 SEP 2021 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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"/>

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 383

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

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

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

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

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

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

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

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

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 SEP 2021 00:01
Patient Cloud Close Date & Time	29 SEP 2021 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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="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"/>

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 OCT 2021 00:01
Patient Cloud Close Date & Time	06 OCT 2021 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 OCT 2021 00:01
Patient Cloud Close Date & Time	20 OCT 2021 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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"/>

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

Patient Cloud Open Date & Time	23 OCT 2021 00:01
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Patient Cloud Close Date & Time	27 OCT 2021 23:59
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US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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°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 ☐

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 NOV 2021 00:01
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Patient Cloud Close Date & Time	17 NOV 2021 23:59
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US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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"/>

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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"/>

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 DEC 2021 00:01
Patient Cloud Close Date & Time	29 DEC 2021 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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="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"/>

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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"/>

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JAN 2022 00:01
Patient Cloud Close Date & Time	02 FEB 2022 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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="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"/>

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 FEB 2022 00:01
Patient Cloud Close Date & Time	09 FEB 2022 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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 ☐

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

Date and time of submission	
Patient Cloud Open Date & Time	19 FEB 2022 00:01
Patient Cloud Close Date & Time	23 FEB 2022 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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="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"/>

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 551

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

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

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

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

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

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

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

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

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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 ☐

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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 ☐

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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°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 ☐

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 579

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

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

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

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

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

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

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

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

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

09 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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 ☐

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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	16 APR 2022 00:01
Patient Cloud Close Date & Time	20 APR 2022 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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 ☐

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

Date and time of submission	
Patient Cloud Open Date & Time	23 APR 2022 00:01
Patient Cloud Close Date & Time	27 APR 2022 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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"/>

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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"/>

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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="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"/>

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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"/>

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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="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"/>

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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"/>

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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"/>

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 656

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

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

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

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

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

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

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

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

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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"/>

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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 ☐

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUL 2022 00:01
Patient Cloud Close Date & Time	20 JUL 2022 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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"/>

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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"/>

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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"/>

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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="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"/>

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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"/>

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 719

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

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

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

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

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

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

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

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

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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="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"/>

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 SEP 2022 00:01
Patient Cloud Close Date & Time	07 SEP 2022 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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="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"/>

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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="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"/>

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 747

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

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

No ☐

Yes ☐

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

Fever (Temperature \geq 100.4°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 ☐

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Open Date & Time](#)

01 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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="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"/>

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

[Patient Cloud Open Date & Time](#)

08 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 775

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

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

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

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

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

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

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

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

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 OCT 2022 00:01
Patient Cloud Close Date & Time	26 OCT 2022 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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°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 ☐

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 OCT 2022 00:01
Patient Cloud Close Date & Time	02 NOV 2022 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

DAY 789

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

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

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

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

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

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

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

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

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

05 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2022 23:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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"/>

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 NOV 2022 00:01
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Patient Cloud Close Date & Time	16 NOV 2022 23:59
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US3352349

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:15:59

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		09 APR 2021 05:02:55

US3352349

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 15:02:00

Generated On: 09 Jun 2021 17:15:59

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 2 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3352349

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 15:02:00

Generated On: 09 Jun 2021 17:15:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352349

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 15:02:00

Generated On: 09 Jun 2021 17:15:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3352349

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 15:02:00

Generated On: 09 Jun 2021 17:15:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352349

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 15:02:00

Generated On: 09 Jun 2021 17:15:59

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 3 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3352349

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 15:02:00

Generated On: 09 Jun 2021 17:15:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352349

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 15:02:00

Generated On: 09 Jun 2021 17:15:59

Was Contact Attempted? Yes ☒ No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 8 MAR 2021

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

Comments 3 ATTEMPTS MADE. UNABLE TO REACH.

If Contact Not Made, please provide Comments

US3352349

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 15:02:00

Generated On: 09 Jun 2021 17:15:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352349

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 15:04:25

Generated On: 09 Jun 2021 17:15:59

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

Visit date (dd MMM yyyy)	26 APR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3352349

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 15:04:25

Generated On: 09 Jun 2021 17:15:59

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 APR 2021
Time of assessment (00:00-23:59)	10:13 (24 HR)
Vital Signs Date and Time (derived)	26 APR 2021 10:13
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	94 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3352349

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 15:04:25

Generated On: 09 Jun 2021 17:15:59

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.

US3352349

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 15:04:25

Generated On: 09 Jun 2021 17:15:59

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

Collection date (dd MMM yyyy)	26 APR 2021
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Collection time (00:00-23:59)	10:43 (24 HR)
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Collection date and time (derived)	26 APR 2021 10:43
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US3352349

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 15:04:25

Generated On: 09 Jun 2021 17:15:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352349

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

Was Contact Attempted? Yes ☐
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3352349

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3352349

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:15:59

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"/>

US3352349

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:15:59

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3352349

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

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 15:02:00

Generated On: 09 Jun 2021 17:15:59

Was this visit performed? Yes ☒ No ☐

Visit date (dd MMM yyyy) 03 FEB 2021

Was visit performed at the participant's home or at the clinic? Home ☐ Clinic ☒

Folder OID UNBLND_DECIDE

US3352349

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

Form: Unblinding

Data signed: (b) (4) 28 Apr 2021 15:02:00

Generated On: 09 Jun 2021 17:15:59

Date of updated informed consent (<i>dd MMM yyyy</i>)	03 FEB 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	03 FEB 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3352349

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 28 Apr 2021 15:02:00

Generated On: 09 Jun 2021 17:15:59

Height	
Weight	
BMI (xxx.x)	

US3352349

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Apr 2021 15:02:00

Generated On: 09 Jun 2021 17:15:59

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	03 FEB 2021
Time of assessment (00:00-23:59)	10:17 (24 HR)
Vital Signs Date and Time (derived)	03 FEB 2021 10:17
Temperature (xxx.x)	37.2 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3352349

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 15:02:00

Generated On: 09 Jun 2021 17:15:59

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	03 FEB 2021
Time of assessment (00:00-23:59)	11:38 (24 HR)
Vital Signs Date and Time (derived)	03 FEB 2021 11:38
Temperature (xxx.x)	37.3 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	100 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3352349

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

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 15:02:00

Generated On: 09 Jun 2021 17:15:59

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.

US3352349

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

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 15:02:00

Generated On: 09 Jun 2021 17:15:59

Was study treatment given? Yes ☒
No ☐

If No, reason not given

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

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 03 FEB 2021

What was the treatment time? (00:00-23:59) 11:08 (24 HR)

Treatment Date and Time (derived) 03 FEB 2021 11:08

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

US3352349

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 15:02:00

Generated On: 09 Jun 2021 17:15:59

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

Collection date (dd MMM yyyy)	03 FEB 2021
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Collection time (00:00-23:59)	10:42 (24 HR)
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Collection date and time (derived)	03 FEB 2021 10:42
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US3352349

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 28 Apr 2021 15:02:00

Generated On: 09 Jun 2021 17:15:59

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	03 FEB 2021
Collection time (00:00 - 23:59)	10:39
Collection Date and Time (derived)	03 FEB 2021 10:39

US3352349

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

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 15:02:00

Generated On: 09 Jun 2021 17:15:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352349

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 15:02:00

Generated On: 09 Jun 2021 17:15:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3352349

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 15:02:00

Generated On: 09 Jun 2021 17:15:59

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

US3352349

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:15:59

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

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

Folder OID	
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US3352349

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

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

US3352349

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
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	

US3352349

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:15:59

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.

US3352349

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

Was study treatment given? Yes ☐
No ☐

If No, reason not given

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

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

What was the study treatment? (Unblinded) _____

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? _____

US3352349

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 15:02:00

Generated On: 09 Jun 2021 17:15:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352349

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

Was Contact Attempted? Yes ☐
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3352349

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 15:02:00

Generated On: 09 Jun 2021 17:15:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352349

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 15:02:00

Generated On: 09 Jun 2021 17:15:59

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

Visit date (dd MMM yyyy)	26 APR 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	OLD57
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US3352349

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 15:02:00

Generated On: 09 Jun 2021 17:15:59

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 APR 2021
Time of assessment (00:00-23:59)	10:13 (24 HR)
Vital Signs Date and Time (derived)	26 APR 2021 10:13
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	94 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3352349

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 15:02:00

Generated On: 09 Jun 2021 17:15:59

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.

US3352349

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 15:02:00

Generated On: 09 Jun 2021 17:15:59

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

Collection date (dd MMM yyyy)	26 APR 2021
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Collection time (00:00-23:59)	10:43 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	26 APR 2021 10:43
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US3352349

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 28 Apr 2021 15:02:00

Generated On: 09 Jun 2021 17:15:59

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3352349

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

AEID	USA-US066-2021-MRNA-1273-P30 1000010
Adverse event	UNSPECIFIED LIVER INFECTION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	26 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	24 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	26 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	26 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input checked="" type="radio"/>
Number of Days in ICU	

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US3352349

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3352349

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

SUBJECT WAS CONTACTED IN
REGARDS IN SCHEDULING HIS
OPEN LABEL DAY 29 VISIT.
SUBJECT STATED HE WILL NOT
BE COMING IN DUE TO A
PROLONGATION OF
HOSPITALIZATION. SUBJECT
STATED HE WAS DIAGNOSED
WITH A LIVER INFECTION. HE
ALSO SAID THAT CURRENTLY
HE WAS RECEIVING
ANTIBIOTICS THROUGH AN IV
BUT WAS UNAWARE OF THE
ANTIBIOTICS NAME. MEDICAL
RECORDS WILL BE
REQUESTED.

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3352349

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 28 Apr 2021 15:02:00

Generated On: 09 Jun 2021 17:15:59

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

Yes ☐

No ☒

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

US3352349

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 28 Apr 2021 15:02:00

Generated On: 09 Jun 2021 17:15:59

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3352349

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:15:59

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3352349

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:15:59

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 ☐

US3352349

Folder: SAE USA-US066-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

SAEID	USA-US066-2021-MRNA-1273-P301000010
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SURISADAY
Investigator's Last Name	MEDEROS
Site Address: Street	9299 SW 152 ST
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33031
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3352349

Folder: SAE USA-US066-2021-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:15:59

SAEID	USA-US066-2021-MRNA-1273-P301000010
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SURISADAY
Investigator's Last Name	MEDEROS
Site Address: Street	9299 SW 152 ST
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33031
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	02/APR/2021 11:48
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3352349

Folder: SAE USA-US066-2021-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:15:59

SAEID	USA-US066-2021-MRNA-1273-P301000010
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SURISADAY
Investigator's Last Name	MEDEROS
Site Address: Street	9299 SW 152 ST
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33031
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	29/APR/2021 05:56
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3352349 (Prod: Research Centers of America - ERG)

US3352349

Form: Participant Creation

Generated On: 09 Jun 2021 17:15:59

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:18:21
User entered 'US3352349'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 18:24:50

US3352349

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:15:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:38:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 14:54:48

US3352349

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:38:13
User entered '10 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 18:24:51

US3352349

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:38:13
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	11 Sep 2020 14:54:48

US3352349

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:15:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User entered 'SCRN'	System	11 Sep 2020 14:54:48

US3352349

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:15:59

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:38:41
User entered (b) (6) 1969'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 18:24:52

US3352349

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:15:59

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:38:41
User entered '51'	(b) (4), (b) (6)	11 Sep 2020 14:55:12

US3352349

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:15:59

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User entered 'YEARS'	System	11 Sep 2020 14:55:12

US3352349

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:15:59

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User entered '51'	System	10 Sep 2020 19:44:42

US3352349

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:15:59

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:38:41
User closed query 'Per GCL Lab Reconciliation: Swab for Visit1 Day1 Sex (Male) recorded on this form does not match with the Sex (Female) reported in PPD Central lab. Please reconcile the correct Sex and update if confirmed. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 10:22:47
Query 'Per GCL Lab Reconciliation: Swab for Visit1 Day1 Sex (Male) recorded on this form does not match with the Sex (Female) reported in PPD Central lab. Please reconcile the correct Sex and update if confirmed. Else clarify, thank you.' answered with 'data confirmed' (Site from DM).	Matthew Muniz (b) (4)	22 Oct 2020 13:11:37
User opened query 'Per GCL Lab Reconciliation: Swab for Visit1 Day1 Sex (Male) recorded on this form does not match with the Sex (Female) reported in PPD Central lab. Please reconcile the correct Sex and update if confirmed. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 11:17:29
User entered 'Male (M)'	(b) (4), (b) (6)	11 Sep 2020 14:55:12

US3352349

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:15:59

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:38:41
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4), (b) (6)	11 Sep 2020 14:55:12

US3352349

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:15:59

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:38:41
User entered 'l'	(b) (4), (b) (6)	11 Sep 2020 14:55:12

US3352349

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:15:59

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:38:41
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 14:55:12

US3352349

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:15:59

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:38:41
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 14:55:12

US3352349

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:15:59

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:38:41
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 14:55:12

US3352349

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:15:59

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:38:41
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 14:55:12

US3352349

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:15:59

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:38:41
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 14:55:12

US3352349

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:15:59

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:38:41
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 14:55:12

US3352349

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:15:59

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:38:41
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 14:55:12

US3352349

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:15:59

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:38:41
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 14:55:12

US3352349

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:38:23
User entered '10 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 19:44:42

US3352349

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User entered 'Sep 2020'	System	10 Sep 2020 19:44:42

US3352349

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User entered '2020'	System	10 Sep 2020 19:44:42

US3352349

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:15:59

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:38:23
User entered 'Amendment 3 (3)'	(b) (4), (b) (6)	10 Sep 2020 19:44:42

US3352349

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:38:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 19:44:42

US3352349

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:38:23
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 19:44:42

US3352349

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:15:59

[If reason for screen fail is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:38:23
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 19:44:42

US3352349

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:15:59

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:38:23
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 19:44:42

US3352349

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:15:59

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:38:23
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 18:24:51

US3352349

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:15:59

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User entered 'I'	System	10 Sep 2020 19:44:48

US3352349

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:48:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 19:44:48

US3352349

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:15:59

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
User closed query 'Per source, Obesity is listed in Medical History. Please add to EDC Medical History.' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 15:37:02
Query 'Per source, Obesity is listed in Medical History. Please add to EDC Medical History.' answered with 'DATA UPDATED' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 16:54:22
User opened query 'Per source, Obesity is listed in Medical History. Please add to EDC Medical History.' (Site from CRA).	(b) (4), (b) (6)	14 Dec 2020 18:43:57
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:42:54
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 14:56:06
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 14:55:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 14:55:24

US3352349

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:15:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:46:35
User coded data point as SOC: Social circumstances, HLT: Lifestyle issues, HLT: Alcohol product use, PT: Alcohol use, LLT: Alcohol use - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 14:58:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 14:58:37
Data point term sent to Coder	System	11 Sep 2020 14:57:16
User entered 'Alcohol Consumption'	(b) (4), (b) (6)	11 Sep 2020 14:56:31

US3352349

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:46:35
User entered 'un UNK 1986'	(b) (4), (b) (6)	11 Sep 2020 14:56:31

US3352349

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:15:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:46:35
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 14:56:31

US3352349

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:15:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:46:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 14:56:31

US3352349

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:46:35
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 14:56:31

US3352349

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:15:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:46:35
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 14:56:31

US3352349

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User entered 'Jan 1986'	System	11 Sep 2020 14:56:31

US3352349

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User entered '1986'	System	11 Sep 2020 14:56:31

US3352349

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User entered empty.	System	11 Sep 2020 14:56:31

US3352349

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User entered empty.	System	11 Sep 2020 14:56:31

US3352349

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:15:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:56:32
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4)	05 Mar 2021 17:09:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Mar 2021 17:09:55
Data point term sent to Coder	System	05 Mar 2021 16:54:35
User entered 'OBESITY'	(b) (4), (b) (6)	05 Mar 2021 16:53:45

US3352349

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:56:32
User entered 'UN May 2020'	(b) (4), (b) (6)	05 Mar 2021 16:53:45

US3352349

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:15:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:56:32
User entered '0'	(b) (4), (b) (6)	05 Mar 2021 16:53:45

US3352349

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:15:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:56:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Mar 2021 16:53:45

US3352349

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:56:32
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 16:53:45

US3352349

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:15:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:56:32
User entered '0'	(b) (4), (b) (6)	05 Mar 2021 16:53:45

US3352349

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User entered 'May 2020'	System	05 Mar 2021 16:53:45

US3352349

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User entered '2020'	System	05 Mar 2021 16:53:45

US3352349

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User entered empty.	System	05 Mar 2021 16:53:45

US3352349

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User entered empty.	System	05 Mar 2021 16:53:45

US3352349

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:42:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 14:57:29

US3352349

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:42:04
User entered '10 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 14:57:29

US3352349

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:42:04
User entered '14:04'	(b) (4), (b) (6)	11 Sep 2020 14:57:29

US3352349

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User entered '10 Sep 2020 14:04'	System	11 Sep 2020 14:57:29

US3352349

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:42:04
User entered '168' cm	(b) (4), (b) (6)	11 Sep 2020 14:57:29
DataPoint set to visible.	System	10 Sep 2020 19:44:48

US3352349

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:42:04
User entered '89.8' kg	(b) (4), (b) (6)	11 Sep 2020 14:57:29
DataPoint set to visible.	System	10 Sep 2020 19:44:48

US3352349

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User entered '31.81689'	System	11 Sep 2020 14:57:29
DataPoint set to visible.	System	10 Sep 2020 19:44:48

US3352349

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User entered 'kg/m2'	System	11 Sep 2020 14:57:29
DataPoint set to visible.	System	10 Sep 2020 19:44:48

US3352349

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:42:04
User entered missing code ND - Not Done.	(b) (4), (b) (6)	11 Sep 2020 14:57:29

US3352349

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:42:04
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 14:57:29

US3352349

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:42:04
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 14:57:29

US3352349

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:42:04
User entered missing code ND - Not Done.	(b) (4), (b) (6)	11 Sep 2020 14:57:29

US3352349

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User entered 'bpm'	System	11 Sep 2020 14:57:29

US3352349

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:42:04
User entered missing code ND - Not Done.	(b) (4), (b) (6)	11 Sep 2020 14:57:29

US3352349

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User entered 'breaths/min'	System	11 Sep 2020 14:57:29

US3352349

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:42:04
User entered missing code ND - Not Done.	(b) (4), (b) (6)	11 Sep 2020 14:57:29

US3352349

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User entered 'mmHg'	System	11 Sep 2020 14:57:29

US3352349

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:42:04
User entered missing code ND - Not Done.	(b) (4), (b) (6)	11 Sep 2020 14:57:29

US3352349

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User entered 'mmHg'	System	11 Sep 2020 14:57:29

US3352349

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31

US3352349

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31

US3352349

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:15:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:49:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 14:57:37

US3352349

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:15:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:49:15
User entered '10 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 14:57:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:40:53
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 14:58:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:40:51
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 14:58:12

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Folder: Screening

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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)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:40:50
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 14:58:12

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Folder: Screening

Form: Risk of Exposure

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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)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:40:48
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 14:58:12

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:40:45
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 14:58:12

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Folder: Screening

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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)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:40:44
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 14:58:12

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Folder: Screening

Form: Risk of Exposure

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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)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:40:42
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 14:58:12

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[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)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:40:40
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 14:58:12

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:15:59

[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)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:40:38
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 14:58:12

US3352349

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:15:59

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)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:40:35
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 14:58:12

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:15:59

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)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:40:33
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 14:58:12

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:15:59

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:39:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 14:58:12

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:15:59

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:39:18
User entered 'Frequent group bike riding'	(b) (4), (b) (6)	11 Sep 2020 14:58:12

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Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 14:58:12

US3352349

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:40:31
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 14:58:12

US3352349

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:15:59

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)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:40:29
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 14:58:12

US3352349

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:15:59

[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)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:37:21
User closed query 'Per source, subject resides in High Density housing. Please verify with source and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 15:37:19
Query 'Per source, subject resides in High Density housing. Please verify with source and update EDC accordingly.' answered with 'DATA UPDATED' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 16:55:13
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 16:54:56
User opened query 'Per source, subject resides in High Density housing. Please verify with source and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	14 Dec 2020 18:39:57
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 14:58:12

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:15:59

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)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:39:59
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 14:58:12

US3352349

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:37:26
User closed query 'Per source, subject does not reside in a single family home. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 15:37:24
Query 'Per source, subject does not reside in a single family home. Please verify and update EDC accordingly.' answered with 'DATA UPDATED' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 16:55:29
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 16:54:56
User opened query 'Per source, subject does not reside in a single family home. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	14 Dec 2020 18:40:23
User entered '1'	(b) (4), (b) (6)	11 Sep 2020 14:58:12

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:15:59

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 14:58:12

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:19:31
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:40:25
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 14:58:12

US3352349

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:15:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:14:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 14:58:27

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:14:54
User entered '10 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 14:58:27

US3352349

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:14:54
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	11 Sep 2020 14:58:27

US3352349

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:15:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User entered 'VISIT1'	System	11 Sep 2020 14:58:27

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:15:09
User entered '10 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 18:54:47

US3352349

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:15:59

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:15:09
User entered '113137'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 18:54:47

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Folder: Visit 1 Day 1

Form: Randomization

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:15:09
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 18:54:47

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Folder: Visit 1 Day 1

Form: Randomization

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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)	30 Apr 2021 08:01:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:15:09
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 14:58:45

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Folder: Visit 1 Day 1

Form: Randomization

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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)	30 Apr 2021 08:01:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:15:09
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 14:58:45

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Folder: Visit 1 Day 1

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[Severe obesity \(body mass index > or = 40kg/m2\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:15:09
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 14:58:45

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Folder: Visit 1 Day 1

Form: Randomization

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:15:09
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 14:58:45

US3352349

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:15:59

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:15:09
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 14:58:45

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Folder: Visit 1 Day 1

Form: Randomization

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Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:15:09
User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 11:28:35
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'updated' (Site from DM).	Matthew Muniz (b) (4)	05 Nov 2020 18:41:35
User entered 'No (N)'	Matthew Muniz (b) (4)	05 Nov 2020 18:41:30
User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 15:51:40
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 06:02:26
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:02:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:15:59

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:42:18
User entered missing code ND - Not Done.	(b) (4), (b) (6)	11 Sep 2020 15:00:18

US3352349

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:15:59

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:42:16
User entered missing code ND - Not Done.	(b) (4), (b) (6)	11 Sep 2020 15:00:18

US3352349

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:15:59

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:42:18
User entered missing code ND - Not Done.	(b) (4), (b) (6)	11 Sep 2020 15:00:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:15:59

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:42:16
User entered missing code ND - Not Done.	(b) (4), (b) (6)	11 Sep 2020 15:00:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	11 Sep 2020 15:00:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:42:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 15:00:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:42:25
User entered '10 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 15:00:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:42:28
User entered '14:04'	(b) (4), (b) (6)	11 Sep 2020 15:00:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User entered '10 Sep 2020 14:04'	System	11 Sep 2020 15:00:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:42:32
User entered '37.0' C	(b) (4), (b) (6)	11 Sep 2020 15:00:18

US3352349

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:42:35
User entered 'Oral (Oral)'	(b) (4), (b) (6)	11 Sep 2020 15:00:18

US3352349

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:42:37
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 15:00:18

US3352349

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:42:39
User entered '75'	(b) (4), (b) (6)	11 Sep 2020 15:00:18

US3352349

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User entered 'bpm'	System	11 Sep 2020 15:00:18

US3352349

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:42:43
User entered '15'	(b) (4), (b) (6)	11 Sep 2020 15:00:18

US3352349

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User entered 'breaths/min'	System	11 Sep 2020 15:00:18

US3352349

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:42:45
User entered '123'	(b) (4), (b) (6)	11 Sep 2020 15:00:18

US3352349

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User entered 'mmHg'	System	11 Sep 2020 15:00:18

US3352349

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:42:46
User entered '86'	(b) (4), (b) (6)	11 Sep 2020 15:00:18

US3352349

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User entered 'mmHg'	System	11 Sep 2020 15:00:18

US3352349

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:15:59

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:42:18
User entered missing code ND - Not Done.	(b) (4), (b) (6)	11 Sep 2020 15:00:18

US3352349

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:15:59

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 18:42:16
User entered missing code ND - Not Done.	(b) (4), (b) (6)	11 Sep 2020 15:00:18

US3352349

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	11 Sep 2020 15:00:18

US3352349

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:16:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 15:00:18

US3352349

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:16:23
User entered '10 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 15:00:18

US3352349

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 15:37:53
User closed query 'Per source, post-dose vitals were taken at 15:46. Please verify with source and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 15:37:51
Query 'Per source, post-dose vitals were taken at 15:46. Please verify with source and update EDC accordingly.' answered with 'DATA UPDATED' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 16:58:59
User entered '15:46' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 16:58:39
User opened query 'Per source, post-dose vitals were taken at 15:46. Please verify with source and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	14 Dec 2020 19:17:30
User closed query 'Per CDM: Time difference between dosing and post-dose vital signs assessment is less than 30 minutes. According to protocol, post-dose vital signs should be measured at least 30 minutes after IP injection. Please reconcile and update as needed.' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 21:14:38
Query 'Per CDM: Time difference between dosing and post-dose vital signs assessment is less than 30 minutes. According to protocol, post-dose vital signs should be measured at least 30 minutes after IP injection. Please reconcile and update as needed.' answered with 'deviation to be filed data correct as entered' (Site from DM).	Matthew Muniz (b) (4)	07 Oct 2020 19:46:14
User opened query 'Per CDM: Time difference between dosing and post-dose vital signs assessment is less than 30 minutes. According to protocol, post-dose vital signs should be measured at least 30 minutes after IP injection. Please reconcile and update as needed.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 17:00:32
User entered '14:46'	(b) (4), (b) (6)	11 Sep 2020 15:00:18

US3352349

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User entered '10 Sep 2020 15:46'	System	05 Mar 2021 16:58:39
User entered '10 Sep 2020 14:46'	System	11 Sep 2020 15:00:18

US3352349

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:19:42
User entered '36.8' C	(b) (4), (b) (6)	11 Sep 2020 15:00:18

US3352349

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:19:43
User entered 'Oral (Oral)'	(b) (4), (b) (6)	11 Sep 2020 15:00:18

US3352349

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:19:45
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 15:00:18

US3352349

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:19:47
User entered '93'	(b) (4), (b) (6)	11 Sep 2020 15:00:18

US3352349

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User entered 'bpm'	System	11 Sep 2020 15:00:18

US3352349

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:19:49
User entered '15'	(b) (4), (b) (6)	11 Sep 2020 15:00:18

US3352349

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User entered 'breaths/min'	System	11 Sep 2020 15:00:18

US3352349

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:19:51
User entered '112'	(b) (4), (b) (6)	11 Sep 2020 15:00:18

US3352349

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User entered 'mmHg'	System	11 Sep 2020 15:00:18

US3352349

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:19:54
User entered '83'	(b) (4), (b) (6)	11 Sep 2020 15:00:18

US3352349

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User entered 'mmHg'	System	11 Sep 2020 15:00:18

US3352349

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:15:59

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 14:53:36
User closed query 'Please mark Physical Examination performed as "No". Since Screening and Day 1 Visit 1 occurred on the same day, only 1 entry for PE is required between the two.' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 14:53:26
Query 'Please mark Physical Examination performed as "No". Since Screening and Day 1 Visit 1 occurred on the same day, only 1 entry for PE is required between the two.' answered with 'updated' (Site from CRA).	Matthew Muniz (b) (4)	14 Dec 2020 19:25:00
User entered 'No (N)' reason for change: Data Entry Error	Matthew Muniz (b) (4)	14 Dec 2020 19:24:41
User opened query 'Please mark Physical Examination performed as "No". Since Screening and Day 1 Visit 1 occurred on the same day, only 1 entry for PE is required between the two.' (Site from CRA).	(b) (4), (b) (6)	14 Dec 2020 19:22:17
DataPoint Un-verified.	(b) (4), (b) (6)	14 Dec 2020 19:20:12
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:20:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 15:00:25

US3352349

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:15:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 14:53:36
User entered empty; reason for change Data Entry Error	Matthew Muniz (b) (4)	14 Dec 2020 19:24:41
DataPoint Un-verified.	(b) (4), (b) (6)	14 Dec 2020 19:20:13
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:20:06
User entered '10 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 15:00:25

US3352349

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:15:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 19:45:21

US3352349

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:15:40
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 19:45:21

US3352349

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

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)	30 Apr 2021 08:01:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:15:40
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 19:45:21

US3352349

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User entered 'MRNA-1273 OR PLACEBO'	System	10 Sep 2020 19:45:21

US3352349

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:15:40
User entered '10 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 19:45:21

US3352349

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:15:40
User entered '15:16'	(b) (4), (b) (6)	10 Sep 2020 19:45:21

US3352349

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User entered '10 Sep 2020 15:16'	System	10 Sep 2020 19:45:21

US3352349

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:15:40
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	10 Sep 2020 19:45:21

US3352349

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:15:40
User entered 'ONCE'	System	10 Sep 2020 19:45:21

US3352349

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User entered 'INTRAMUSCULAR'	System	10 Sep 2020 19:45:21

US3352349

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:15:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:23:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 15:00:51

US3352349

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:15:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:23:47
User entered '10 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 15:00:51

US3352349

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:23:47
User entered '14:43'	(b) (4), (b) (6)	11 Sep 2020 15:00:51

US3352349

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User entered '10 Sep 2020 14:43'	System	11 Sep 2020 15:00:51

US3352349

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:24:14
User entered '10 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 15:01:06

US3352349

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:15:59

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	11 Sep 2020 15:01:06

US3352349

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:15:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:24:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 15:01:06

US3352349

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:24:14
User entered '14:38'	(b) (4), (b) (6)	11 Sep 2020 15:01:06

US3352349

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User entered '10 Sep 2020 14:38'	System	11 Sep 2020 15:01:06

US3352349

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:15:59

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	11 Sep 2020 15:01:06

US3352349

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:15:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:24:14
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 15:06:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Sep 2020 15:06:14
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 15:06:14
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 15:01:06
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 15:01:06

US3352349

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:15:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:24:14
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 15:01:06

US3352349

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User entered empty.	System	11 Sep 2020 15:01:06

US3352349

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:24:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 14:54:01

US3352349

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:01:09
User entered 'I'	System	11 Sep 2020 14:54:01

US3352349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
Data entry locked.	System	10 Sep 2020 19:45:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-10T15:47:37', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'bb505204-e39a-4710-bf94-09fbb274fa52'	System	10 Sep 2020 19:48:32
User entered 'Yes (Y)'	System	10 Sep 2020 19:48:32

US3352349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-10T15:48:12', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'bb505204-e39a-4710-bf94-09fbb274fa52'	System	10 Sep 2020 19:48:32
User entered '97.5'	System	10 Sep 2020 19:48:32

US3352349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-10T15:48:22', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'bb505204-e39a-4710-bf94-09fbb274fa52'	System	10 Sep 2020 19:48:32
User entered 'No (N)'	System	10 Sep 2020 19:48:32

US3352349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-10T15:48:26', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'bb505204-e39a-4710-bf94-09fbb274fa52'	System	10 Sep 2020 19:48:32
User entered '10 Sep 2020 15:48'	System	10 Sep 2020 19:48:32

US3352349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '10 Sep 2020 15:36'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '10 Sep 2020 18:06'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
Data entry locked.	System	10 Sep 2020 19:45:21
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-10T19:55:19', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '687eb3c1-daad-4148-82a5-2ee692a43c62'	System	10 Sep 2020 23:55:56
User entered 'Yes (Y)'	System	10 Sep 2020 23:55:56

US3352349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-10T19:55:31', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '687eb3c1-daad-4148-82a5-2ee692a43c62'	System	10 Sep 2020 23:55:56
User entered '97.0'	System	10 Sep 2020 23:55:56

US3352349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-10T19:55:38', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '687eb3c1-daad-4148-82a5-2ee692a43c62'	System	10 Sep 2020 23:55:56
User entered 'No (N)'	System	10 Sep 2020 23:55:56

US3352349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-10T19:55:53', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '687eb3c1-daad-4148-82a5-2ee692a43c62'	System	10 Sep 2020 23:55:56
User entered '10 Sep 2020 19:55'	System	10 Sep 2020 23:55:56

US3352349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '10 Sep 2020 19:01'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
Data entry locked.	System	10 Sep 2020 19:45:21
User entered 'Day 2'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:15:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-11T19:30:00', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '7baee273-8064-4e63-88c1-1f33a50dcf82'	System	11 Sep 2020 23:30:35
User entered 'Yes (Y)'	System	11 Sep 2020 23:30:35

US3352349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:15:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-11T19:30:13', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '7baee273-8064-4e63-88c1-1f33a50dcf82'	System	11 Sep 2020 23:30:35
User entered '99.0'	System	11 Sep 2020 23:30:35

US3352349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-11T19:30:18', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '7baee273-8064-4e63-88c1-1f33a50dcf82'	System	11 Sep 2020 23:30:35
User entered 'No (N)'	System	11 Sep 2020 23:30:35

US3352349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:15:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-11T19:30:29', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '7baee273-8064-4e63-88c1-1f33a50dcf82'	System	11 Sep 2020 23:30:35
User entered '11 Sep 2020 19:30'	System	11 Sep 2020 23:30:35

US3352349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
Data entry locked.	System	10 Sep 2020 19:45:21
User entered 'Day 3'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:15:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-12T23:45:10', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'e6b31422-6e84-48c7-a798-258f204c83de'	System	13 Sep 2020 03:45:25
User entered 'Yes (Y)'	System	13 Sep 2020 03:45:25

US3352349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:15:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-12T23:45:16', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'e6b31422-6e84-48c7-a798-258f204c83de' User entered '97.1'	System	13 Sep 2020 03:45:25
	System	13 Sep 2020 03:45:25

US3352349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-12T23:45:21', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'e6b31422-6e84-48c7-a798-258f204c83de'	System	13 Sep 2020 03:45:25
User entered 'No (N)'	System	13 Sep 2020 03:45:25

US3352349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:15:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-12T23:45:24', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'e6b31422-6e84-48c7-a798-258f204c83de'	System	13 Sep 2020 03:45:25
User entered '12 Sep 2020 23:45'	System	13 Sep 2020 03:45:25

US3352349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
Data entry locked.	System	10 Sep 2020 19:45:21
User entered 'Day 4'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:15:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-13T19:12:20', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'b5334088-1ab5-425c-9d98-fb6a4deef82a'	System	13 Sep 2020 23:12:46
User entered 'Yes (Y)'	System	13 Sep 2020 23:12:46

US3352349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:15:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-13T19:12:38', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'b5334088-1ab5-425c-9d98-fb6a4deef82a'	System	13 Sep 2020 23:12:46
User entered '96.5'	System	13 Sep 2020 23:12:46

US3352349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-13T19:12:41', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'b5334088-1ab5-425c-9d98-fb6a4deef82a'	System	13 Sep 2020 23:12:46
User entered 'No (N)'	System	13 Sep 2020 23:12:46

US3352349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:15:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-13T19:12:45', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'b5334088-1ab5-425c-9d98-fb6a4deef82a'	System	13 Sep 2020 23:12:46
User entered '13 Sep 2020 19:12'	System	13 Sep 2020 23:12:46

US3352349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
Data entry locked.	System	10 Sep 2020 19:45:21
User entered 'Day 5'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:15:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-14T23:36:20', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'fbcd1c94-fd70-481a-8353-717c53953a9b'	System	15 Sep 2020 03:36:32
User entered 'Yes (Y)'	System	15 Sep 2020 03:36:32

US3352349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:15:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-14T23:36:24', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'fbed1c94-fd70-481a-8353-717c53953a9b'	System	15 Sep 2020 03:36:32
User entered '96.7'	System	15 Sep 2020 03:36:32

US3352349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-14T23:36:28', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'fbcd1c94-fd70-481a-8353-717c53953a9b'	System	15 Sep 2020 03:36:32
User entered 'No (N)'	System	15 Sep 2020 03:36:32

US3352349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:15:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-14T23:36:31', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'fbcd1c94-fd70-481a-8353-717c53953a9b'	System	15 Sep 2020 03:36:32
User entered '14 Sep 2020 23:36'	System	15 Sep 2020 03:36:32

US3352349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
Data entry locked.	System	10 Sep 2020 19:45:21
User entered 'Day 6'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:15:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-16T03:19:16', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'ac178ab2-cbe1-49c3-a38f-2a1b12bbe0b3'	System	16 Sep 2020 07:20:26
User entered 'Yes (Y)'	System	16 Sep 2020 07:20:26

US3352349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:15:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-16T03:20:16', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'ac178ab2-cbe1-49c3-a38f-2a1b12bbe0b3'	System	16 Sep 2020 07:20:26
User entered '97.6'	System	16 Sep 2020 07:20:26

US3352349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-16T03:20:20', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'ac178ab2-cbe1-49c3-a38f-2a1b12bbe0b3'	System	16 Sep 2020 07:20:26
User entered 'No (N)'	System	16 Sep 2020 07:20:26

US3352349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:15:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-16T03:20:24', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'ac178ab2-cbe1-49c3-a38f-2a1b12bbe0b3'	System	16 Sep 2020 07:20:26
User entered '16 Sep 2020 03:20'	System	16 Sep 2020 07:20:26

US3352349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
Data entry locked.	System	10 Sep 2020 19:45:21
User entered 'Day 7'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:15:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-16T18:28:01', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'c79a9d43-31d4-4bfb-ba52-42e371d87db5'	System	16 Sep 2020 22:28:32
User entered 'Yes (Y)'	System	16 Sep 2020 22:28:32

US3352349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:15:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-16T18:28:16', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'c79a9d43-31d4-4bfb-ba52-42e371d87db5'	System	16 Sep 2020 22:28:32
User entered '97.6'	System	16 Sep 2020 22:28:32

US3352349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-16T18:28:23', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'c79a9d43-31d4-4bfb-ba52-42e371d87db5'	System	16 Sep 2020 22:28:32
User entered 'No (N)'	System	16 Sep 2020 22:28:32

US3352349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:15:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-16T18:28:26', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'c79a9d43-31d4-4bfb-ba52-42e371d87db5'	System	16 Sep 2020 22:28:32
User entered '16 Sep 2020 18:28'	System	16 Sep 2020 22:28:32

US3352349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
Data entry locked.	System	10 Sep 2020 19:45:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-10T15:48:34', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'a53d8840-8c69-45c9-8832-d1542cfe6707'	System	10 Sep 2020 19:48:52
User entered 'None (1)'	System	10 Sep 2020 19:48:52

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-10T15:48:38', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'a53d8840-8c69-45c9-8832-d1542cfe6707'	System	10 Sep 2020 19:48:52
User entered 'No (N)'	System	10 Sep 2020 19:48:52

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-10T15:48:40', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'a53d8840-8c69-45c9-8832-d1542cfe6707'	System	10 Sep 2020 19:48:52
User entered 'No (N)'	System	10 Sep 2020 19:48:52

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-10T15:48:46', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'a53d8840-8c69-45c9-8832-d1542cfe6707'	System	10 Sep 2020 19:48:52
User entered 'None (1)'	System	10 Sep 2020 19:48:52

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-10T15:48:49', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'a53d8840-8c69-45c9-8832-d1542cfe6707'	System	10 Sep 2020 19:48:52
User entered '10 Sep 2020 15:48'	System	10 Sep 2020 19:48:52

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '10 Sep 2020 15:36'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '10 Sep 2020 18:06'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
Data entry locked.	System	10 Sep 2020 19:45:21
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-10T19:56:00', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'cc15ffba-dfb7-4b1d-ae64-5143a5b83d9d'	System	10 Sep 2020 23:56:17
User entered 'None (1)'	System	10 Sep 2020 23:56:17

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-10T19:56:04', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'cc15ffba-dfb7-4b1d-ae64-5143a5b83d9d'	System	10 Sep 2020 23:56:17
User entered 'No (N)'	System	10 Sep 2020 23:56:17

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-10T19:56:07', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'cc15ffba-dfb7-4b1d-ae64-5143a5b83d9d'	System	10 Sep 2020 23:56:17
User entered 'No (N)'	System	10 Sep 2020 23:56:17

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-10T19:56:10', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'cc15ffba-dfb7-4b1d-ae64-5143a5b83d9d'	System	10 Sep 2020 23:56:17
User entered 'None (1)'	System	10 Sep 2020 23:56:17

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-10T19:56:14', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'cc15ffba-dfb7-4b1d-ae64-5143a5b83d9d'	System	10 Sep 2020 23:56:17
User entered '10 Sep 2020 19:56'	System	10 Sep 2020 23:56:17

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '10 Sep 2020 19:01'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
Data entry locked.	System	10 Sep 2020 19:45:21
User entered 'Day 2'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:15:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-11T19:31:52', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'c4c6315f-e2e1-40df-8526-259cb173ff84'	System	11 Sep 2020 23:31:58
User entered 'None (1)'	System	11 Sep 2020 23:31:58

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:15:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-11T19:31:08', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'c4c6315f-e2e1-40df-8526-259cb173ff84'	System	11 Sep 2020 23:31:58
User entered 'No (N)'	System	11 Sep 2020 23:31:58

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-11T19:31:17', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'c4c6315f-e2e1-40df-8526-259cb173ff84'	System	11 Sep 2020 23:31:58
User entered 'No (N)'	System	11 Sep 2020 23:31:58

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:15:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-11T19:31:25', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'c4c6315f-e2e1-40df-8526-259cb173ff84'	System	11 Sep 2020 23:31:58
User entered 'None (1)'	System	11 Sep 2020 23:31:58

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:15:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-11T19:31:55', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'c4c6315f-e2e1-40df-8526-259cb173ff84'	System	11 Sep 2020 23:31:58
User entered '11 Sep 2020 19:31'	System	11 Sep 2020 23:31:58

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
Data entry locked.	System	10 Sep 2020 19:45:21
User entered 'Day 3'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:15:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-12T23:45:32', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '8d6753c3-d53a-4f7d-8d30-341094ffbbc9'	System	13 Sep 2020 03:45:49
User entered 'None (1)'	System	13 Sep 2020 03:45:49

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:15:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-12T23:45:37', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '8d6753c3-d53a-4f7d-8d30-341094ffbbc9'	System	13 Sep 2020 03:45:49
User entered 'No (N)'	System	13 Sep 2020 03:45:49

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-12T23:45:40', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '8d6753c3-d53a-4f7d-8d30-341094ffbbc9'	System	13 Sep 2020 03:45:49
User entered 'No (N)'	System	13 Sep 2020 03:45:49

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:15:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-12T23:45:45', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '8d6753c3-d53a-4f7d-8d30-341094ffbbc9'	System	13 Sep 2020 03:45:49
User entered 'None (1)'	System	13 Sep 2020 03:45:49

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:15:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-12T23:45:47', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '8d6753c3-d53a-4f7d-8d30-341094ffbbc9'	System	13 Sep 2020 03:45:49
User entered '12 Sep 2020 23:45'	System	13 Sep 2020 03:45:49

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
Data entry locked.	System	10 Sep 2020 19:45:21
User entered 'Day 4'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:15:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-13T19:12:49', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '1ef47d9d-6d29-473c-9d5c-491a77f47153'	System	13 Sep 2020 23:13:01
User entered 'None (1)'	System	13 Sep 2020 23:13:01

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:15:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-13T19:12:52', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '1ef47d9d-6d29-473c-9d5c-491a77f47153'	System	13 Sep 2020 23:13:01
User entered 'No (N)'	System	13 Sep 2020 23:13:01

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-13T19:12:54', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '1ef47d9d-6d29-473c-9d5c-491a77f47153'	System	13 Sep 2020 23:13:01
User entered 'No (N)'	System	13 Sep 2020 23:13:01

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:15:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-13T19:12:57', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '1ef47d9d-6d29-473c-9d5c-491a77f47153'	System	13 Sep 2020 23:13:01
User entered 'None (1)'	System	13 Sep 2020 23:13:01

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:15:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-13T19:12:59', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '1ef47d9d-6d29-473c-9d5c-491a77f47153'	System	13 Sep 2020 23:13:01
User entered '13 Sep 2020 19:12'	System	13 Sep 2020 23:13:01

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
Data entry locked.	System	10 Sep 2020 19:45:21
User entered 'Day 5'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:15:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-14T23:36:01', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '73743338-de64-41d1-ada1-61cd7a9e1418'	System	15 Sep 2020 03:36:19
User entered 'None (1)'	System	15 Sep 2020 03:36:19

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:15:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-14T23:36:03', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '73743338-de64-41d1-ada1-61cd7a9e1418'	System	15 Sep 2020 03:36:19
User entered 'No (N)'	System	15 Sep 2020 03:36:19

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-14T23:36:06', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '73743338-de64-41d1-ada1-61cd7a9e1418'	System	15 Sep 2020 03:36:19
User entered 'No (N)'	System	15 Sep 2020 03:36:19

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:15:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-14T23:36:12', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '73743338-de64-41d1-ada1-61cd7a9e1418'	System	15 Sep 2020 03:36:19
User entered 'None (1)'	System	15 Sep 2020 03:36:19

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:15:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-14T23:36:16', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '73743338-de64-41d1-ada1-61cd7a9e1418'	System	15 Sep 2020 03:36:19
User entered '14 Sep 2020 23:36'	System	15 Sep 2020 03:36:19

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
Data entry locked.	System	10 Sep 2020 19:45:21
User entered 'Day 6'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:15:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-16T03:20:35', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'c412501c-89d4-4235-a9af-22e020a1f640'	System	16 Sep 2020 07:20:48
User entered 'None (1)'	System	16 Sep 2020 07:20:48

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:15:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-16T03:20:39', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'c412501c-89d4-4235-a9af-22e020a1f640'	System	16 Sep 2020 07:20:48
User entered 'No (N)'	System	16 Sep 2020 07:20:48

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-16T03:20:42', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'c412501c-89d4-4235-a9af-22e020a1f640'	System	16 Sep 2020 07:20:48
User entered 'No (N)'	System	16 Sep 2020 07:20:48

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:15:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-16T03:20:44', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'c412501c-89d4-4235-a9af-22e020a1f640'	System	16 Sep 2020 07:20:48
User entered 'None (1)'	System	16 Sep 2020 07:20:48

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:15:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-16T03:20:47', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'c412501c-89d4-4235-a9af-22e020a1f640'	System	16 Sep 2020 07:20:48
User entered '16 Sep 2020 03:20'	System	16 Sep 2020 07:20:48

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
Data entry locked.	System	10 Sep 2020 19:45:21
User entered 'Day 7'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:15:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-16T18:28:30', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '342fc0f9-be88-4b31-baba-9fe8549efe94'	System	16 Sep 2020 22:28:46
User entered 'None (1)'	System	16 Sep 2020 22:28:46

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:15:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-16T18:28:34', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '342fc0f9-be88-4b31-baba-9fe8549efe94'	System	16 Sep 2020 22:28:46
User entered 'No (N)'	System	16 Sep 2020 22:28:46

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-16T18:28:36', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '342fc0f9-be88-4b31-baba-9fe8549efe94'	System	16 Sep 2020 22:28:46
User entered 'No (N)'	System	16 Sep 2020 22:28:46

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:15:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-16T18:28:42', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '342fc0f9-be88-4b31-baba-9fe8549efe94'	System	16 Sep 2020 22:28:46
User entered 'None (1)'	System	16 Sep 2020 22:28:46

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:15:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-16T18:28:45', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '342fc0f9-be88-4b31-baba-9fe8549efe94'	System	16 Sep 2020 22:28:46
User entered '16 Sep 2020 18:28'	System	16 Sep 2020 22:28:46

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
Data entry locked.	System	10 Sep 2020 19:45:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-10T15:48:55', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '46dcfabd-69c0-4517-b026-6e4a6b44b477'	System	10 Sep 2020 19:49:20
User entered 'None (0)'	System	10 Sep 2020 19:49:20

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-10T15:48:57', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '46dcfabd-69c0-4517-b026-6e4a6b44b477'	System	10 Sep 2020 19:49:20
User entered 'None (0)'	System	10 Sep 2020 19:49:20

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-10T15:49:01', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '46dcfabd-69c0-4517-b026-6e4a6b44b477'	System	10 Sep 2020 19:49:20
User entered 'None (0)'	System	10 Sep 2020 19:49:20

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-10T15:49:04', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '46dcfabd-69c0-4517-b026-6e4a6b44b477'	System	10 Sep 2020 19:49:20
User entered 'None (0)'	System	10 Sep 2020 19:49:20

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-10T15:49:07', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '46dcfabd-69c0-4517-b026-6e4a6b44b477'	System	10 Sep 2020 19:49:20
User entered 'None (0)'	System	10 Sep 2020 19:49:20

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-10T15:49:09', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '46dcfabd-69c0-4517-b026-6e4a6b44b477'	System	10 Sep 2020 19:49:20
User entered 'None (0)'	System	10 Sep 2020 19:49:20

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-10T15:49:12', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '46dcfabd-69c0-4517-b026-6e4a6b44b477'	System	10 Sep 2020 19:49:20
User entered 'No (N)'	System	10 Sep 2020 19:49:20

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-10T15:49:16', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '46dcfabd-69c0-4517-b026-6e4a6b44b477'	System	10 Sep 2020 19:49:20
User entered '10 Sep 2020 15:49'	System	10 Sep 2020 19:49:20

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '10 Sep 2020 15:36'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '10 Sep 2020 18:06'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
Data entry locked.	System	10 Sep 2020 19:45:21
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-10T19:56:19', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'ee62d45c-2bbd-4275-88d6-57cdf07ca172'	System	10 Sep 2020 23:56:41
User entered 'None (0)'	System	10 Sep 2020 23:56:41

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-10T19:56:21', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'ee62d45c-2bbd-4275-88d6-57cdf07ca172'	System	10 Sep 2020 23:56:41
User entered 'None (0)'	System	10 Sep 2020 23:56:41

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-10T19:56:24', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'ee62d45c-2bbd-4275-88d6-57cdf07ca172'	System	10 Sep 2020 23:56:41
User entered 'None (0)'	System	10 Sep 2020 23:56:41

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-10T19:56:26', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'ee62d45c-2bbd-4275-88d6-57cdf07ca172'	System	10 Sep 2020 23:56:41
User entered 'None (0)'	System	10 Sep 2020 23:56:41

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-10T19:56:29', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'ee62d45c-2bbd-4275-88d6-57cdf07ca172'	System	10 Sep 2020 23:56:41
User entered 'None (0)'	System	10 Sep 2020 23:56:41

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-10T19:56:32', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'ee62d45c-2bbd-4275-88d6-57cdf07ca172'	System	10 Sep 2020 23:56:41
User entered 'None (0)'	System	10 Sep 2020 23:56:41

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-10T19:56:36', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'ee62d45c-2bbd-4275-88d6-57cdf07ca172'	System	10 Sep 2020 23:56:41
User entered 'No (N)'	System	10 Sep 2020 23:56:41

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-10T19:56:39', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'ee62d45c-2bbd-4275-88d6-57cdf07ca172'	System	10 Sep 2020 23:56:41
User entered '10 Sep 2020 19:56'	System	10 Sep 2020 23:56:41

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '10 Sep 2020 19:01'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
Data entry locked.	System	10 Sep 2020 19:45:21
User entered 'Day 2'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:15:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-11T19:32:02', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '68f3187d-646a-4b26-94cf-e4d4d9e384fb'	System	11 Sep 2020 23:32:33
User entered 'None (0)'	System	11 Sep 2020 23:32:33

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:15:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-11T19:32:05', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '68f3187d-646a-4b26-94cf-e4d4d9e384fb'	System	11 Sep 2020 23:32:33
User entered 'None (0)'	System	11 Sep 2020 23:32:33

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:15:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-11T19:32:10', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '68f3187d-646a-4b26-94cf-e4d4d9e384fb'	System	11 Sep 2020 23:32:33
User entered 'None (0)'	System	11 Sep 2020 23:32:33

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:15:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-11T19:32:15', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '68f3187d-646a-4b26-94cf-e4d4d9e384fb'	System	11 Sep 2020 23:32:33
User entered 'None (0)'	System	11 Sep 2020 23:32:33

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:15:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-11T19:32:18', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '68f3187d-646a-4b26-94cf-e4d4d9e384fb'	System	11 Sep 2020 23:32:33
User entered 'None (0)'	System	11 Sep 2020 23:32:33

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:15:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-11T19:32:21', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '68f3187d-646a-4b26-94cf-e4d4d9e384fb'	System	11 Sep 2020 23:32:33
User entered 'None (0)'	System	11 Sep 2020 23:32:33

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-11T19:32:28', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '68f3187d-646a-4b26-94cf-e4d4d9e384fb'	System	11 Sep 2020 23:32:33
User entered 'No (N)'	System	11 Sep 2020 23:32:33

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:15:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-11T19:32:31', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '68f3187d-646a-4b26-94cf-e4d4d9e384fb'	System	11 Sep 2020 23:32:33
User entered '11 Sep 2020 19:32'	System	11 Sep 2020 23:32:33

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
Data entry locked.	System	10 Sep 2020 19:45:21
User entered 'Day 3'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:15:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-12T23:45:51', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'a02c91da-4462-4e77-a2cb-d02f92736a96'	System	13 Sep 2020 03:46:10
User entered 'None (0)'	System	13 Sep 2020 03:46:10

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:15:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-12T23:45:54', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'a02c91da-4462-4e77-a2cb-d02f92736a96'	System	13 Sep 2020 03:46:10
User entered 'None (0)'	System	13 Sep 2020 03:46:10

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:15:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-12T23:45:56', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'a02c91da-4462-4e77-a2cb-d02f92736a96'	System	13 Sep 2020 03:46:10
User entered 'None (0)'	System	13 Sep 2020 03:46:10

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:15:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-12T23:45:58', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'a02c91da-4462-4e77-a2cb-d02f92736a96'	System	13 Sep 2020 03:46:10
User entered 'None (0)'	System	13 Sep 2020 03:46:10

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:15:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-12T23:46:00', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'a02c91da-4462-4e77-a2cb-d02f92736a96'	System	13 Sep 2020 03:46:10
User entered 'None (0)'	System	13 Sep 2020 03:46:10

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:15:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-12T23:46:02', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'a02c91da-4462-4e77-a2cb-d02f92736a96'	System	13 Sep 2020 03:46:10
User entered 'None (0)'	System	13 Sep 2020 03:46:10

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-12T23:46:05', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'a02c91da-4462-4e77-a2cb-d02f92736a96'	System	13 Sep 2020 03:46:10
User entered 'No (N)'	System	13 Sep 2020 03:46:10

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:15:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-12T23:46:07', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'a02c91da-4462-4e77-a2cb-d02f92736a96'	System	13 Sep 2020 03:46:10
User entered '12 Sep 2020 23:46'	System	13 Sep 2020 03:46:10

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
Data entry locked.	System	10 Sep 2020 19:45:21
User entered 'Day 4'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:15:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-13T19:13:03', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'c4736af3-fd32-45b9-b358-05ea811cd1e9'	System	13 Sep 2020 23:13:18
User entered 'None (0)'	System	13 Sep 2020 23:13:18

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:15:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-13T19:13:05', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'c4736af3-fd32-45b9-b358-05ea811cd1e9'	System	13 Sep 2020 23:13:18
User entered 'None (0)'	System	13 Sep 2020 23:13:18

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:15:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-13T19:13:07', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'c4736af3-fd32-45b9-b358-05ea811cd1e9'	System	13 Sep 2020 23:13:18
User entered 'None (0)'	System	13 Sep 2020 23:13:18

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:15:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-13T19:13:09', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'c4736af3-fd32-45b9-b358-05ea811cd1e9'	System	13 Sep 2020 23:13:18
User entered 'None (0)'	System	13 Sep 2020 23:13:18

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:15:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-13T19:13:11', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'c4736af3-fd32-45b9-b358-05ea811cd1e9'	System	13 Sep 2020 23:13:18
User entered 'None (0)'	System	13 Sep 2020 23:13:18

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:15:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-13T19:13:13', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'c4736af3-fd32-45b9-b358-05ea811cd1e9'	System	13 Sep 2020 23:13:18
User entered 'None (0)'	System	13 Sep 2020 23:13:18

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-13T19:13:15', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'c4736af3-fd32-45b9-b358-05ea811cd1e9'	System	13 Sep 2020 23:13:18
User entered 'No (N)'	System	13 Sep 2020 23:13:18

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:15:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-13T19:13:17', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'c4736af3-fd32-45b9-b358-05ea811cd1e9'	System	13 Sep 2020 23:13:18
User entered '13 Sep 2020 19:13'	System	13 Sep 2020 23:13:18

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
Data entry locked.	System	10 Sep 2020 19:45:21
User entered 'Day 5'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:15:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-14T23:35:41', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '0e03972f-58eb-4849-879e-a98fb4d9d46b'	System	15 Sep 2020 03:36:02
User entered 'None (0)'	System	15 Sep 2020 03:36:02

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:15:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-14T23:35:43', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '0e03972f-58eb-4849-879e-a98fb4d9d46b'	System	15 Sep 2020 03:36:02
User entered 'None (0)'	System	15 Sep 2020 03:36:02

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:15:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-14T23:35:45', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '0e03972f-58eb-4849-879e-a98fb4d9d46b'	System	15 Sep 2020 03:36:02
User entered 'None (0)'	System	15 Sep 2020 03:36:02

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:15:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-14T23:35:46', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '0e03972f-58eb-4849-879e-a98fb4d9d46b'	System	15 Sep 2020 03:36:02
User entered 'None (0)'	System	15 Sep 2020 03:36:02

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:15:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-14T23:35:47', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '0e03972f-58eb-4849-879e-a98fb4d9d46b'	System	15 Sep 2020 03:36:02
User entered 'None (0)'	System	15 Sep 2020 03:36:02

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:15:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-14T23:35:49', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '0e03972f-58eb-4849-879e-a98fb4d9d46b'	System	15 Sep 2020 03:36:02
User entered 'None (0)'	System	15 Sep 2020 03:36:02

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-14T23:35:55', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '0e03972f-58eb-4849-879e-a98fb4d9d46b'	System	15 Sep 2020 03:36:02
User entered 'No (N)'	System	15 Sep 2020 03:36:02

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:15:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-14T23:35:58', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '0e03972f-58eb-4849-879e-a98fb4d9d46b'	System	15 Sep 2020 03:36:02
User entered '14 Sep 2020 23:35'	System	15 Sep 2020 03:36:02

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
Data entry locked.	System	10 Sep 2020 19:45:21
User entered 'Day 6'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:15:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-16T03:20:51', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '05032b9d-3d37-4050-9004-45c663d49378'	System	16 Sep 2020 07:21:11
User entered 'None (0)'	System	16 Sep 2020 07:21:11

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:15:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-16T03:20:53', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '05032b9d-3d37-4050-9004-45c663d49378'	System	16 Sep 2020 07:21:11
User entered 'None (0)'	System	16 Sep 2020 07:21:11

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:15:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-16T03:20:55', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '05032b9d-3d37-4050-9004-45c663d49378'	System	16 Sep 2020 07:21:11
User entered 'None (0)'	System	16 Sep 2020 07:21:11

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:15:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-16T03:20:58', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '05032b9d-3d37-4050-9004-45c663d49378'	System	16 Sep 2020 07:21:11
User entered 'None (0)'	System	16 Sep 2020 07:21:11

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:15:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-16T03:21:00', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '05032b9d-3d37-4050-9004-45c663d49378'	System	16 Sep 2020 07:21:11
User entered 'None (0)'	System	16 Sep 2020 07:21:11

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:15:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-16T03:21:03', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '05032b9d-3d37-4050-9004-45c663d49378'	System	16 Sep 2020 07:21:11
User entered 'None (0)'	System	16 Sep 2020 07:21:11

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-16T03:21:06', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '05032b9d-3d37-4050-9004-45c663d49378'	System	16 Sep 2020 07:21:11
User entered 'No (N)'	System	16 Sep 2020 07:21:11

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:15:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-16T03:21:09', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '05032b9d-3d37-4050-9004-45c663d49378'	System	16 Sep 2020 07:21:11
User entered '16 Sep 2020 03:21'	System	16 Sep 2020 07:21:11

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
Data entry locked.	System	10 Sep 2020 19:45:21
User entered 'Day 7'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:15:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-16T18:28:50', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'c15087ed-7aed-4ab9-82d2-ce392facc6b9'	System	16 Sep 2020 22:29:09
User entered 'None (0)'	System	16 Sep 2020 22:29:09

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:15:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-16T18:28:52', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'c15087ed-7aed-4ab9-82d2-ce392facc6b9'	System	16 Sep 2020 22:29:09
User entered 'None (0)'	System	16 Sep 2020 22:29:09

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:15:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-16T18:28:55', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'c15087ed-7aed-4ab9-82d2-ce392facc6b9'	System	16 Sep 2020 22:29:09
User entered 'None (0)'	System	16 Sep 2020 22:29:09

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:15:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-16T18:28:57', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'c15087ed-7aed-4ab9-82d2-ce392facc6b9'	System	16 Sep 2020 22:29:09
User entered 'None (0)'	System	16 Sep 2020 22:29:09

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:15:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-16T18:28:59', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'c15087ed-7aed-4ab9-82d2-ce392facc6b9'	System	16 Sep 2020 22:29:09
User entered 'None (0)'	System	16 Sep 2020 22:29:09

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:15:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-16T18:29:01', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'c15087ed-7aed-4ab9-82d2-ce392facc6b9'	System	16 Sep 2020 22:29:09
User entered 'None (0)'	System	16 Sep 2020 22:29:09

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-16T18:29:03', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'c15087ed-7aed-4ab9-82d2-ce392facc6b9'	System	16 Sep 2020 22:29:09
User entered 'No (N)'	System	16 Sep 2020 22:29:09

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:15:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-09-16T18:29:07', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'c15087ed-7aed-4ab9-82d2-ce392facc6b9'	System	16 Sep 2020 22:29:09
User entered '16 Sep 2020 18:29'	System	16 Sep 2020 22:29:09

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 19:45:21

US3352349

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 19:45:21

US3352349

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:25:42
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:13:13
User entered 'Yes (Y)'	Surisaday Mederos (b) (4)	18 Sep 2020 17:46:05

US3352349

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:25:42
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:13:13
User entered '18 Sep 2020'	Surisaday Mederos (b) (4)	18 Sep 2020 17:46:05

US3352349

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:25:42
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:13:13
User entered 'Contact Made (CONTACT MADE)'	Surisaday Mederos (b) (4)	18 Sep 2020 17:46:05

US3352349

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:25:42
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:13:13
User entered empty.	Surisaday Mederos (b) (4)	18 Sep 2020 17:46:05
	(b) (4)	

US3352349

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:25:42
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:13:37
User entered 'Yes (Y)'	Surisaday Mederos (b) (4)	18 Sep 2020 17:46:10

US3352349

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:25:42
User entered 'I'	System	18 Sep 2020 17:46:10

US3352349

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:38:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:14:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Sep 2020 14:24:13

US3352349

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:38:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:14:19
User entered '26 Sep 2020'	(b) (4), (b) (6)	26 Sep 2020 14:24:13

US3352349

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:38:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:14:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	26 Sep 2020 14:24:13

US3352349

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:38:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:14:19
User entered empty.	(b) (4), (b) (6)	26 Sep 2020 14:24:13

US3352349

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:38:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:14:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Sep 2020 14:24:17

US3352349

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:38:13
User entered 'I'	System	26 Sep 2020 14:24:17

US3352349

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:05:24
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:15:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 20:09:25

US3352349

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:05:24
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:15:06
User entered '2 Oct 2020'	(b) (4), (b) (6)	02 Oct 2020 20:09:25

US3352349

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:05:24
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:15:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	02 Oct 2020 20:09:25

US3352349

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:05:24
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:15:06
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 20:09:25

US3352349

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:05:24
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:15:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 20:09:29

US3352349

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:05:24
User entered 'I'	System	02 Oct 2020 20:09:29

US3352349

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:15:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:04:32
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:27:42
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	08 Oct 2020 20:51:54

US3352349

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:04:32
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:27:42
User entered '8 Oct 2020'	Matthew Muniz (b) (4)	08 Oct 2020 20:51:54

US3352349

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:04:32
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:27:42
User entered 'Clinic (Clinic)'	Matthew Muniz (b) (4)	08 Oct 2020 20:51:54

US3352349

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:15:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:04:32
User entered 'VISIT2'	System	08 Oct 2020 20:51:54

US3352349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:04:32
User accepted default value 'Pre-Dose (PREDOSE)'	Matthew Muniz (b) (4)	08 Oct 2020 20:53:08

US3352349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:04:32
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:29:54
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	08 Oct 2020 20:53:08

US3352349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:04:32
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:29:57
User entered '8 Oct 2020'	Matthew Muniz (b) (4)	08 Oct 2020 20:53:08

US3352349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:04:32
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:30:06
User entered '13:16'	Matthew Muniz (b) (4)	08 Oct 2020 20:53:08

US3352349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:04:32
User entered '8 Oct 2020 13:16'	System	08 Oct 2020 20:53:08

US3352349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:04:32
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:30:09
User entered '37.0' C	Matthew Muniz (b) (4)	08 Oct 2020 20:53:08

US3352349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:04:32
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:30:12
User entered 'Oral (Oral)'	Matthew Muniz (b) (4)	08 Oct 2020 20:53:08

US3352349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:04:32
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:30:14
User entered empty.	Matthew Muniz (b) (4)	08 Oct 2020 20:53:08

US3352349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:04:32
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:30:16
User entered '102'	Matthew Muniz (b) (4)	08 Oct 2020 20:53:08

US3352349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:04:32
User entered 'bpm'	System	08 Oct 2020 20:53:08

US3352349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:04:32
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:30:18
User entered '15'	Matthew Muniz (b) (4)	08 Oct 2020 20:53:08

US3352349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:04:32
User entered 'breaths/min'	System	08 Oct 2020 20:53:08

US3352349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:04:32
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:30:20
User entered '156'	Matthew Muniz (b) (4)	08 Oct 2020 20:53:08

US3352349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:04:32
User entered 'mmHg'	System	08 Oct 2020 20:53:08

US3352349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:04:32
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:30:22
User entered '90'	Matthew Muniz (b) (4)	08 Oct 2020 20:53:08

US3352349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:04:32
User entered 'mmHg'	System	08 Oct 2020 20:53:08

US3352349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:04:32
User accepted default value 'Post-Dose (POSTDOSE)'	Matthew Muniz (b) (4)	08 Oct 2020 20:53:08

US3352349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:04:32
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:32:51
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	08 Oct 2020 20:53:08

US3352349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:04:32
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:32:53
User entered '8 Oct 2020'	Matthew Muniz (b) (4)	08 Oct 2020 20:53:08

US3352349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:04:32
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:32:57
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Oct 2020 20:53:17
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Oct 2020 20:53:17
User entered '15:10' reason for change: Data Entry Error	Matthew Muniz (b) (4)	08 Oct 2020 20:53:17
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Oct 2020 20:53:08
User entered empty.	Matthew Muniz (b) (4)	08 Oct 2020 20:53:08

US3352349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:04:32
User entered '8 Oct 2020 15:10'	System	08 Oct 2020 20:53:17
User entered empty.	System	08 Oct 2020 20:53:08

US3352349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:04:32
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:33:00
User entered '36.8' C	Matthew Muniz (b) (4)	08 Oct 2020 20:53:08

US3352349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:04:32
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:33:03
User entered 'Oral (Oral)'	Matthew Muniz (b) (4)	08 Oct 2020 20:53:08

US3352349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:04:32
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:33:04
User entered empty.	Matthew Muniz (b) (4)	08 Oct 2020 20:53:08

US3352349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:04:32
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:33:08
User entered '94'	Matthew Muniz (b) (4)	08 Oct 2020 20:53:08

US3352349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:04:32
User entered 'bpm'	System	08 Oct 2020 20:53:08

US3352349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:04:32
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:33:10
User entered '16'	Matthew Muniz (b) (4)	08 Oct 2020 20:53:08

US3352349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:04:32
User entered 'breaths/min'	System	08 Oct 2020 20:53:08

US3352349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:04:32
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:33:13
User entered '143'	Matthew Muniz (b) (4)	08 Oct 2020 20:53:08

US3352349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:04:32
User entered 'mmHg'	System	08 Oct 2020 20:53:08

US3352349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:04:32
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:33:15
User entered '97'	Matthew Muniz (b) (4)	08 Oct 2020 20:53:08

US3352349

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:04:32
User entered 'mmHg'	System	08 Oct 2020 20:53:08

US3352349

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:15:59

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:04:32
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 14:54:17
User closed query 'Per source, no Physical Exam was completed and it was not required. Please verify with source and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 14:54:13
Query 'Per source, no Physical Exam was completed and it was not required. Please verify with source and update EDC accordingly.' answered with 'Data updated ' (Site from CRA).	Wanda Delgado (b) (4)	20 Jan 2021 19:46:21
User entered 'No (N)' reason for change: Data Entry Error	Wanda Delgado (b) (4)	20 Jan 2021 19:46:09
User opened query 'Per source, no Physical Exam was completed and it was not required. Please verify with source and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6)	14 Dec 2020 19:31:27
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	08 Oct 2020 20:53:29

US3352349

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:15:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:04:32
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 14:54:17
User entered empty; reason for change Data Entry Error	Wanda Delgado (b) (4)	20 Jan 2021 19:46:09
User entered '8 Oct 2020'	Matthew Muniz (b) (4)	08 Oct 2020 20:53:29

US3352349

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:04:32
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:32:34
User entered 'Yes (Y)'	Sara Gomez (b) (4)	08 Oct 2020 18:47:36
	(b) (4)	

US3352349

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:04:32
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:32:34
User entered empty.	Sara Gomez (b) (4)	08 Oct 2020 18:47:36
	(b) (4)	

US3352349

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

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)	30 Apr 2021 10:04:32
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:32:34
User entered empty.	Sara Gomez (b) (4) (b) (4)	08 Oct 2020 18:47:36

US3352349

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:04:32
User entered 'MRNA-1273 OR PLACEBO'	System	08 Oct 2020 18:47:36

US3352349

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:04:32
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:32:34
User entered '08 Oct 2020'	Sara Gomez (b) (4)	08 Oct 2020 18:47:36
	(b) (4)	

US3352349

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:04:32
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:32:34
User entered '14:40'	Sara Gomez (b) (4)	08 Oct 2020 18:47:36
	(b) (4)	

US3352349

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:04:32
User entered '08 Oct 2020 14:40'	System	08 Oct 2020 18:47:36

US3352349

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:04:32
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:32:34
User entered 'Left Arm (LEFT ARM)'	Sara Gomez (b) (4)	08 Oct 2020 18:47:36

US3352349

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:04:32
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:32:34
User entered 'ONCE'	System	08 Oct 2020 18:47:36

US3352349

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:04:32
User entered 'INTRAMUSCULAR'	System	08 Oct 2020 18:47:36

US3352349

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:15:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:04:32
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:32:06
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	08 Oct 2020 20:53:51

US3352349

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:15:59

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:04:32
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:32:06
User entered '8 Oct 2020'	Matthew Muniz (b) (4)	08 Oct 2020 20:53:51

US3352349

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:04:32
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:32:06
User entered '13:37'	Matthew Muniz (b) (4)	08 Oct 2020 20:53:51

US3352349

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:04:32
User entered '8 Oct 2020 13:37'	System	08 Oct 2020 20:53:51

US3352349

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:15:59

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:04:32
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:31:57
User entered '8 Oct 2020'	Matthew Muniz (b) (4)	08 Oct 2020 20:54:08

US3352349

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:15:59

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:04:32
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Matthew Muniz (b) (4)	08 Oct 2020 20:54:08

US3352349

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:15:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:04:32
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:31:57
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	08 Oct 2020 20:54:08

US3352349

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:15:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:04:32
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:31:57
User entered '13:33'	Matthew Muniz (b) (4)	08 Oct 2020 20:54:08

US3352349

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:04:32
User entered '8 Oct 2020 13:33'	System	08 Oct 2020 20:54:08

US3352349

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:15:59

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:04:32
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Matthew Muniz (b) (4)	08 Oct 2020 20:54:08

US3352349

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:15:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:04:32
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:31:57
User entered 'No (N)'	Matthew Muniz (b) (4)	08 Oct 2020 20:54:08

US3352349

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:04:32
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:31:57
User entered empty.	Matthew Muniz (b) (4)	08 Oct 2020 20:54:08

US3352349

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:04:32
User entered empty.	System	08 Oct 2020 20:54:08

US3352349

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:04:32
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:36:58
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	08 Oct 2020 20:54:16

US3352349

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:04:32
User entered '1'	System	08 Oct 2020 20:54:16

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
Data entry locked.	System	08 Oct 2020 18:47:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '08 Oct 2020 15:00'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '08 Oct 2020 17:30'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
Data entry locked.	System	08 Oct 2020 18:47:36
User entered 'Day 1, after vaccination (at home)'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-09T10:15:12', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '17255c11-6db5-4237-92e1-9da51b122831'	System	09 Oct 2020 14:15:27
User entered 'Yes (Y)'	System	09 Oct 2020 14:15:27

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-09T10:15:16', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '17255c11-6db5-4237-92e1-9da51b122831'	System	09 Oct 2020 14:15:27
User entered '96.7'	System	09 Oct 2020 14:15:27

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-09T10:15:20', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '17255c11-6db5-4237-92e1-9da51b122831'	System	09 Oct 2020 14:15:27
User entered 'No (N)'	System	09 Oct 2020 14:15:27

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-09T10:15:23', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '17255c11-6db5-4237-92e1-9da51b122831'	System	09 Oct 2020 14:15:27
User entered '09 Oct 2020 10:15'	System	09 Oct 2020 14:15:27

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '08 Oct 2020 18:25'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '09 Oct 2020 11:59'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
Data entry locked.	System	08 Oct 2020 18:47:36
User entered 'Day 2'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:15:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-09T22:10:48', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'ffd3841d-8895-45cd-8300-368a384c75b5'	System	10 Oct 2020 02:11:25
User entered 'Yes (Y)'	System	10 Oct 2020 02:11:25

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:15:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-09T22:11:09', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'ffd3841d-8895-45cd-8300-368a384c75b5'	System	10 Oct 2020 02:11:25
User entered '96.7'	System	10 Oct 2020 02:11:25

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-09T22:11:13', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'ffd3841d-8895-45cd-8300-368a384c75b5'	System	10 Oct 2020 02:11:25
User entered 'No (N)'	System	10 Oct 2020 02:11:25

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:15:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-09T22:11:23', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'ffd3841d-8895-45cd-8300-368a384c75b5'	System	10 Oct 2020 02:11:25
User entered '09 Oct 2020 22:11'	System	10 Oct 2020 02:11:25

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
Data entry locked.	System	08 Oct 2020 18:47:36
User entered 'Day 3'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:15:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-11T09:05:21', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'f73e2968-88d0-4c1c-90a7-cfc7fc5bda91'	System	11 Oct 2020 13:05:48
User entered 'Yes (Y)'	System	11 Oct 2020 13:05:48

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:15:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-11T09:05:31', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'f73e2968-88d0-4c1c-90a7-cfc7fc5bda91'	System	11 Oct 2020 13:05:48
User entered '97.6'	System	11 Oct 2020 13:05:48

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-11T09:05:42', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'f73e2968-88d0-4c1c-90a7-cfc7fc5bda91'	System	11 Oct 2020 13:05:48
User entered 'No (N)'	System	11 Oct 2020 13:05:48

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:15:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-11T09:05:45', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'f73e2968-88d0-4c1c-90a7-cfc7fc5bda91'	System	11 Oct 2020 13:05:48
User entered '11 Oct 2020 09:05'	System	11 Oct 2020 13:05:48

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
Data entry locked.	System	08 Oct 2020 18:47:36
User entered 'Day 4'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:15:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-11T20:06:04', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '42d824f8-14f7-4826-9ddf-2da4ee074218'	System	12 Oct 2020 00:06:43
User entered 'Yes (Y)'	System	12 Oct 2020 00:06:43

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:15:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-11T20:06:22', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '42d824f8-14f7-4826-9ddf-2da4ee074218'	System	12 Oct 2020 00:06:43
User entered '97.8'	System	12 Oct 2020 00:06:43

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-11T20:06:31', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '42d824f8-14f7-4826-9ddf-2da4ee074218'	System	12 Oct 2020 00:06:43
User entered 'No (N)'	System	12 Oct 2020 00:06:43

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:15:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-11T20:06:38', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '42d824f8-14f7-4826-9ddf-2da4ee074218'	System	12 Oct 2020 00:06:43
User entered '11 Oct 2020 20:06'	System	12 Oct 2020 00:06:43

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '11 Oct 2020 12:00'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '12 Oct 2020 11:59'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
Data entry locked.	System	08 Oct 2020 18:47:36
User entered 'Day 5'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:15:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-12T21:30:46', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '9c2c7f30-3631-490b-9e97-20d7e450082e'	System	13 Oct 2020 01:31:19
User entered 'Yes (Y)'	System	13 Oct 2020 01:31:19

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:15:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-12T21:31:05', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '9c2c7f30-3631-490b-9e97-20d7e450082e' User entered '97.4'	System	13 Oct 2020 01:31:19
	System	13 Oct 2020 01:31:19

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-12T21:31:09', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '9c2c7f30-3631-490b-9e97-20d7e450082e'	System	13 Oct 2020 01:31:19
User entered 'No (N)'	System	13 Oct 2020 01:31:19

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:15:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-12T21:31:16', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '9c2c7f30-3631-490b-9e97-20d7e450082e'	System	13 Oct 2020 01:31:19
User entered '12 Oct 2020 21:31'	System	13 Oct 2020 01:31:19

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '12 Oct 2020 12:00'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '13 Oct 2020 11:59'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
Data entry locked.	System	08 Oct 2020 18:47:36
User entered 'Day 6'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:15:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-13T19:50:23', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'c4e6e09a-efe3-40b5-ab15-e29d766b2317'	System	13 Oct 2020 23:50:53
User entered 'Yes (Y)'	System	13 Oct 2020 23:50:53

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:15:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-13T19:50:32', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'c4e6e09a-efe3-40b5-ab15-e29d766b2317'	System	13 Oct 2020 23:50:53
User entered '97.1'	System	13 Oct 2020 23:50:53

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-13T19:50:40', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'c4e6e09a-efe3-40b5-ab15-e29d766b2317'	System	13 Oct 2020 23:50:53
User entered 'No (N)'	System	13 Oct 2020 23:50:53

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:15:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-13T19:50:46', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'c4e6e09a-efe3-40b5-ab15-e29d766b2317'	System	13 Oct 2020 23:50:53
User entered '13 Oct 2020 19:50'	System	13 Oct 2020 23:50:53

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '13 Oct 2020 12:00'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '14 Oct 2020 11:59'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
Data entry locked.	System	08 Oct 2020 18:47:36
User entered 'Day 7'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:15:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-14T18:03:22', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '9045e017-9ddc-4c40-bf04-2be5f58671ff'	System	14 Oct 2020 22:03:43
User entered 'Yes (Y)'	System	14 Oct 2020 22:03:43

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:15:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-14T18:03:31', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '9045e017-9ddc-4c40-bf04-2be5f58671ff'	System	14 Oct 2020 22:03:43
User entered '98.2'	System	14 Oct 2020 22:03:43

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-14T18:03:35', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '9045e017-9ddc-4c40-bf04-2be5f58671ff'	System	14 Oct 2020 22:03:43
User entered 'No (N)'	System	14 Oct 2020 22:03:43

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:15:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-14T18:03:39', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '9045e017-9ddc-4c40-bf04-2be5f58671ff'	System	14 Oct 2020 22:03:43
User entered '14 Oct 2020 18:03'	System	14 Oct 2020 22:03:43

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '14 Oct 2020 12:00'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '15 Oct 2020 11:59'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
Data entry locked.	System	08 Oct 2020 18:47:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '08 Oct 2020 15:00'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '08 Oct 2020 17:30'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
Data entry locked.	System	08 Oct 2020 18:47:36
User entered 'Day 1, after vaccination (at home)'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-09T10:15:30', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '9d7108a0-1799-4bd0-9022-c6d2789df95c'	System	09 Oct 2020 14:15:45
User entered 'None (1)'	System	09 Oct 2020 14:15:45

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-09T10:15:33', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '9d7108a0-1799-4bd0-9022-c6d2789df95c'	System	09 Oct 2020 14:15:45
User entered 'No (N)'	System	09 Oct 2020 14:15:45

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-09T10:15:35', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '9d7108a0-1799-4bd0-9022-c6d2789df95c'	System	09 Oct 2020 14:15:45
User entered 'No (N)'	System	09 Oct 2020 14:15:45

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-09T10:15:37', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '9d7108a0-1799-4bd0-9022-c6d2789df95c'	System	09 Oct 2020 14:15:45
User entered 'None (1)'	System	09 Oct 2020 14:15:45

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-09T10:15:39', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '9d7108a0-1799-4bd0-9022-c6d2789df95c'	System	09 Oct 2020 14:15:45
User entered '09 Oct 2020 10:15'	System	09 Oct 2020 14:15:45

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '08 Oct 2020 18:25'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '09 Oct 2020 11:59'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
Data entry locked.	System	08 Oct 2020 18:47:36
User entered 'Day 2'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:15:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-09T22:11:30', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '342c807f-b02b-47d4-9e52-cd3f63ebcdc5'	System	10 Oct 2020 02:12:19
User entered 'None (1)'	System	10 Oct 2020 02:12:19

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:15:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-09T22:11:43', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '342c807f-b02b-47d4-9e52-cd3f63ebcdc5'	System	10 Oct 2020 02:12:19
User entered 'No (N)'	System	10 Oct 2020 02:12:19

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-09T22:11:49', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '342c807f-b02b-47d4-9e52-cd3f63ebcdc5'	System	10 Oct 2020 02:12:19
User entered 'No (N)'	System	10 Oct 2020 02:12:19

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:15:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-09T22:12:00', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '342c807f-b02b-47d4-9e52-cd3f63ebcdc5'	System	10 Oct 2020 02:12:19
User entered 'None (1)'	System	10 Oct 2020 02:12:19

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:15:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-09T22:12:14', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '342c807f-b02b-47d4-9e52-cd3f63ebcdc5'	System	10 Oct 2020 02:12:19
User entered '09 Oct 2020 22:12'	System	10 Oct 2020 02:12:19

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
Data entry locked.	System	08 Oct 2020 18:47:36
User entered 'Day 3'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:15:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-11T09:05:50', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '05b5a05b-9227-4f8c-a6a0-40eff93c4d93'	System	11 Oct 2020 13:06:02
User entered 'None (1)'	System	11 Oct 2020 13:06:02

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-11T09:05:52', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '05b5a05b-9227-4f8c-a6a0-40eff93c4d93'	System	11 Oct 2020 13:06:02
User entered 'No (N)'	System	11 Oct 2020 13:06:02

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-11T09:05:54', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '05b5a05b-9227-4f8c-a6a0-40eff93c4d93'	System	11 Oct 2020 13:06:02
User entered 'No (N)'	System	11 Oct 2020 13:06:02

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:15:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-11T09:05:56', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '05b5a05b-9227-4f8c-a6a0-40eff93c4d93'	System	11 Oct 2020 13:06:02
User entered 'None (1)'	System	11 Oct 2020 13:06:02

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:15:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-11T09:05:59', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '05b5a05b-9227-4f8c-a6a0-40eff93c4d93'	System	11 Oct 2020 13:06:02
User entered '11 Oct 2020 09:05'	System	11 Oct 2020 13:06:02

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
Data entry locked.	System	08 Oct 2020 18:47:36
User entered 'Day 4'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:15:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-11T20:06:43', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '0eb039e5-e86e-41ac-9524-eed41a448078'	System	12 Oct 2020 00:06:57
User entered 'None (1)'	System	12 Oct 2020 00:06:57

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-11T20:06:45', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '0eb039e5-e86e-41ac-9524-eed41a448078'	System	12 Oct 2020 00:06:57
User entered 'No (N)'	System	12 Oct 2020 00:06:57

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-11T20:06:48', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '0eb039e5-e86e-41ac-9524-eed41a448078'	System	12 Oct 2020 00:06:57
User entered 'No (N)'	System	12 Oct 2020 00:06:57

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:15:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-11T20:06:51', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '0eb039e5-e86e-41ac-9524-eed41a448078'	System	12 Oct 2020 00:06:57
User entered 'None (1)'	System	12 Oct 2020 00:06:57

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:15:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-11T20:06:54', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '0eb039e5-e86e-41ac-9524-eed41a448078'	System	12 Oct 2020 00:06:57
User entered '11 Oct 2020 20:06'	System	12 Oct 2020 00:06:57

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '11 Oct 2020 12:00'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '12 Oct 2020 11:59'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
Data entry locked.	System	08 Oct 2020 18:47:36
User entered 'Day 5'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:15:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-12T21:31:19', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'e171200a-3531-4486-8f5e-ac3693b2e875'	System	13 Oct 2020 01:31:37
User entered 'None (1)'	System	13 Oct 2020 01:31:37

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-12T21:31:22', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'e171200a-3531-4486-8f5e-ac3693b2e875'	System	13 Oct 2020 01:31:37
User entered 'No (N)'	System	13 Oct 2020 01:31:37

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-12T21:31:25', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'e171200a-3531-4486-8f5e-ac3693b2e875'	System	13 Oct 2020 01:31:37
User entered 'No (N)'	System	13 Oct 2020 01:31:37

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:15:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-12T21:31:29', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'e171200a-3531-4486-8f5e-ac3693b2e875'	System	13 Oct 2020 01:31:37
User entered 'None (1)'	System	13 Oct 2020 01:31:37

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:15:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-12T21:31:32', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'e171200a-3531-4486-8f5e-ac3693b2e875'	System	13 Oct 2020 01:31:37
User entered '12 Oct 2020 21:31'	System	13 Oct 2020 01:31:37

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '12 Oct 2020 12:00'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '13 Oct 2020 11:59'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
Data entry locked.	System	08 Oct 2020 18:47:36
User entered 'Day 6'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:15:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-13T19:50:51', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '13365f38-e8fb-47d1-9487-ad9de41cb518'	System	13 Oct 2020 23:51:05
User entered 'None (1)'	System	13 Oct 2020 23:51:05

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:15:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-13T19:50:53', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '13365f38-e8fb-47d1-9487-ad9de41cb518'	System	13 Oct 2020 23:51:05
User entered 'No (N)'	System	13 Oct 2020 23:51:05

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-13T19:50:55', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '13365f38-e8fb-47d1-9487-ad9de41cb518'	System	13 Oct 2020 23:51:05
User entered 'No (N)'	System	13 Oct 2020 23:51:05

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:15:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-13T19:50:58', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '13365f38-e8fb-47d1-9487-ad9de41cb518'	System	13 Oct 2020 23:51:05
User entered 'None (1)'	System	13 Oct 2020 23:51:05

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:15:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-13T19:51:01', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '13365f38-e8fb-47d1-9487-ad9de41cb518'	System	13 Oct 2020 23:51:05
User entered '13 Oct 2020 19:51'	System	13 Oct 2020 23:51:05

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '13 Oct 2020 12:00'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '14 Oct 2020 11:59'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
Data entry locked.	System	08 Oct 2020 18:47:36
User entered 'Day 7'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:15:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-14T18:03:44', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'b233c278-9f05-49dc-9549-6367879583f2'	System	14 Oct 2020 22:04:05
User entered 'None (1)'	System	14 Oct 2020 22:04:05

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-14T18:03:47', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'b233c278-9f05-49dc-9549-6367879583f2'	System	14 Oct 2020 22:04:05
User entered 'No (N)'	System	14 Oct 2020 22:04:05

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-14T18:03:51', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'b233c278-9f05-49dc-9549-6367879583f2'	System	14 Oct 2020 22:04:05
User entered 'No (N)'	System	14 Oct 2020 22:04:05

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:15:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-14T18:03:54', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'b233c278-9f05-49dc-9549-6367879583f2'	System	14 Oct 2020 22:04:05
User entered 'None (1)'	System	14 Oct 2020 22:04:05

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:15:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-14T18:03:57', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'b233c278-9f05-49dc-9549-6367879583f2'	System	14 Oct 2020 22:04:05
User entered '14 Oct 2020 18:03'	System	14 Oct 2020 22:04:05

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '14 Oct 2020 12:00'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '15 Oct 2020 11:59'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
Data entry locked.	System	08 Oct 2020 18:47:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '08 Oct 2020 15:00'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '08 Oct 2020 17:30'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
Data entry locked.	System	08 Oct 2020 18:47:36
User entered 'Day 1, after vaccination (at home)'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-09T10:15:42', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '5bfc29bd-8d81-4181-9f89-2d7ce9198cf5'	System	09 Oct 2020 14:16:01
User entered 'None (0)'	System	09 Oct 2020 14:16:01

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-09T10:15:44', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '5bfc29bd-8d81-4181-9f89-2d7ce9198cf5'	System	09 Oct 2020 14:16:01
User entered 'None (0)'	System	09 Oct 2020 14:16:01

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-09T10:15:45', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '5bfc29bd-8d81-4181-9f89-2d7ce9198cf5'	System	09 Oct 2020 14:16:01
User entered 'None (0)'	System	09 Oct 2020 14:16:01

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-09T10:15:46', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '5bfc29bd-8d81-4181-9f89-2d7ce9198cf5'	System	09 Oct 2020 14:16:01
User entered 'None (0)'	System	09 Oct 2020 14:16:01

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-09T10:15:48', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '5bfc29bd-8d81-4181-9f89-2d7ce9198cf5'	System	09 Oct 2020 14:16:01
User entered 'None (0)'	System	09 Oct 2020 14:16:01

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-09T10:15:49', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '5bfc29bd-8d81-4181-9f89-2d7ce9198cf5'	System	09 Oct 2020 14:16:01
User entered 'None (0)'	System	09 Oct 2020 14:16:01

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-09T10:15:51', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '5bfc29bd-8d81-4181-9f89-2d7ce9198cf5'	System	09 Oct 2020 14:16:01
User entered 'No (N)'	System	09 Oct 2020 14:16:01

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-09T10:15:57', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '5bfc29bd-8d81-4181-9f89-2d7ce9198cf5'	System	09 Oct 2020 14:16:01
User entered '09 Oct 2020 10:15'	System	09 Oct 2020 14:16:01

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '08 Oct 2020 18:25'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '09 Oct 2020 11:59'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
Data entry locked.	System	08 Oct 2020 18:47:36
User entered 'Day 2'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:15:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-09T22:12:20', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '62368ca3-36b0-410a-a18f-2f675422c0a9'	System	10 Oct 2020 02:12:40
User entered 'None (0)'	System	10 Oct 2020 02:12:40

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:15:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-09T22:12:23', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '62368ca3-36b0-410a-a18f-2f675422c0a9'	System	10 Oct 2020 02:12:40
User entered 'None (0)'	System	10 Oct 2020 02:12:40

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:15:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-09T22:12:25', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '62368ca3-36b0-410a-a18f-2f675422c0a9'	System	10 Oct 2020 02:12:40
User entered 'None (0)'	System	10 Oct 2020 02:12:40

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:15:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-09T22:12:27', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '62368ca3-36b0-410a-a18f-2f675422c0a9'	System	10 Oct 2020 02:12:40
User entered 'None (0)'	System	10 Oct 2020 02:12:40

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:15:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-09T22:12:29', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '62368ca3-36b0-410a-a18f-2f675422c0a9'	System	10 Oct 2020 02:12:40
User entered 'None (0)'	System	10 Oct 2020 02:12:40

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:15:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-09T22:12:31', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '62368ca3-36b0-410a-a18f-2f675422c0a9'	System	10 Oct 2020 02:12:40
User entered 'None (0)'	System	10 Oct 2020 02:12:40

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-09T22:12:34', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '62368ca3-36b0-410a-a18f-2f675422c0a9'	System	10 Oct 2020 02:12:40
User entered 'No (N)'	System	10 Oct 2020 02:12:40

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:15:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-09T22:12:37', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '62368ca3-36b0-410a-a18f-2f675422c0a9'	System	10 Oct 2020 02:12:40
User entered '09 Oct 2020 22:12'	System	10 Oct 2020 02:12:40

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
Data entry locked.	System	08 Oct 2020 18:47:36
User entered 'Day 3'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:15:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-11T09:06:02', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '051d0320-f4fe-4d3e-9c91-55e8405b4185'	System	11 Oct 2020 13:06:18
User entered 'None (0)'	System	11 Oct 2020 13:06:18

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:15:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-11T09:06:04', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '051d0320-f4fe-4d3e-9c91-55e8405b4185'	System	11 Oct 2020 13:06:18
User entered 'None (0)'	System	11 Oct 2020 13:06:18

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:15:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-11T09:06:06', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '051d0320-f4fe-4d3e-9c91-55e8405b4185'	System	11 Oct 2020 13:06:18
User entered 'None (0)'	System	11 Oct 2020 13:06:18

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:15:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-11T09:06:08', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '051d0320-f4fe-4d3e-9c91-55e8405b4185'	System	11 Oct 2020 13:06:18
User entered 'None (0)'	System	11 Oct 2020 13:06:18

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:15:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-11T09:06:10', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '051d0320-f4fe-4d3e-9c91-55e8405b4185'	System	11 Oct 2020 13:06:18
User entered 'None (0)'	System	11 Oct 2020 13:06:18

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:15:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-11T09:06:12', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '051d0320-f4fe-4d3e-9c91-55e8405b4185'	System	11 Oct 2020 13:06:18
User entered 'None (0)'	System	11 Oct 2020 13:06:18

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-11T09:06:14', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '051d0320-f4fe-4d3e-9c91-55e8405b4185'	System	11 Oct 2020 13:06:18
User entered 'No (N)'	System	11 Oct 2020 13:06:18

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:15:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-11T09:06:16', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '051d0320-f4fe-4d3e-9c91-55e8405b4185'	System	11 Oct 2020 13:06:18
User entered '11 Oct 2020 09:06'	System	11 Oct 2020 13:06:18

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
Data entry locked.	System	08 Oct 2020 18:47:36
User entered 'Day 4'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:15:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-11T20:06:58', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '9669944f-89c8-429a-974b-1079fa31466d'	System	12 Oct 2020 00:07:19
User entered 'None (0)'	System	12 Oct 2020 00:07:19

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:15:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-11T20:07:01', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '9669944f-89c8-429a-974b-1079fa31466d'	System	12 Oct 2020 00:07:19
User entered 'None (0)'	System	12 Oct 2020 00:07:19

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:15:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-11T20:07:03', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '9669944f-89c8-429a-974b-1079fa31466d'	System	12 Oct 2020 00:07:19
User entered 'None (0)'	System	12 Oct 2020 00:07:19

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:15:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-11T20:07:05', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '9669944f-89c8-429a-974b-1079fa31466d'	System	12 Oct 2020 00:07:19
User entered 'None (0)'	System	12 Oct 2020 00:07:19

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:15:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-11T20:07:07', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '9669944f-89c8-429a-974b-1079fa31466d'	System	12 Oct 2020 00:07:19
User entered 'None (0)'	System	12 Oct 2020 00:07:19

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:15:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-11T20:07:09', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '9669944f-89c8-429a-974b-1079fa31466d'	System	12 Oct 2020 00:07:19
User entered 'None (0)'	System	12 Oct 2020 00:07:19

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-11T20:07:11', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '9669944f-89c8-429a-974b-1079fa31466d'	System	12 Oct 2020 00:07:19
User entered 'No (N)'	System	12 Oct 2020 00:07:19

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:15:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-11T20:07:14', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '9669944f-89c8-429a-974b-1079fa31466d'	System	12 Oct 2020 00:07:19
User entered '11 Oct 2020 20:07'	System	12 Oct 2020 00:07:19

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '11 Oct 2020 12:00'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '12 Oct 2020 11:59'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
Data entry locked.	System	08 Oct 2020 18:47:36
User entered 'Day 5'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:15:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-12T21:31:38', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '3c195e25-798e-4ffc-9ad9-5ce159b6c739'	System	13 Oct 2020 01:31:59
User entered 'None (0)'	System	13 Oct 2020 01:31:59

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:15:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-12T21:31:40', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '3c195e25-798e-4ffc-9ad9-5ce159b6c739'	System	13 Oct 2020 01:31:59
User entered 'None (0)'	System	13 Oct 2020 01:31:59

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:15:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-12T21:31:42', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '3c195e25-798e-4ffc-9ad9-5ce159b6c739'	System	13 Oct 2020 01:31:59
User entered 'None (0)'	System	13 Oct 2020 01:31:59

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:15:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-12T21:31:44', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '3c195e25-798e-4ffc-9ad9-5ce159b6c739'	System	13 Oct 2020 01:31:59
User entered 'None (0)'	System	13 Oct 2020 01:31:59

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:15:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-12T21:31:48', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '3c195e25-798e-4ffc-9ad9-5ce159b6c739'	System	13 Oct 2020 01:31:59
User entered 'None (0)'	System	13 Oct 2020 01:31:59

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:15:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-12T21:31:50', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '3c195e25-798e-4ffc-9ad9-5ce159b6c739'	System	13 Oct 2020 01:31:59
User entered 'None (0)'	System	13 Oct 2020 01:31:59

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-12T21:31:52', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '3c195e25-798e-4ffc-9ad9-5ce159b6c739'	System	13 Oct 2020 01:31:59
User entered 'No (N)'	System	13 Oct 2020 01:31:59

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:15:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-12T21:31:55', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '3c195e25-798e-4ffc-9ad9-5ce159b6c739'	System	13 Oct 2020 01:31:59
User entered '12 Oct 2020 21:31'	System	13 Oct 2020 01:31:59

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '12 Oct 2020 12:00'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '13 Oct 2020 11:59'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
Data entry locked.	System	08 Oct 2020 18:47:36
User entered 'Day 6'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:15:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-13T19:51:05', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '8483daea-f117-4e22-933c-55691075b516'	System	13 Oct 2020 23:51:36
User entered 'None (0)'	System	13 Oct 2020 23:51:36

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:15:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-13T19:51:07', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '8483daea-f117-4e22-933c-55691075b516'	System	13 Oct 2020 23:51:36
User entered 'None (0)'	System	13 Oct 2020 23:51:36

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:15:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-13T19:51:12', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '8483daea-f117-4e22-933c-55691075b516'	System	13 Oct 2020 23:51:36
User entered 'None (0)'	System	13 Oct 2020 23:51:36

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:15:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-13T19:51:15', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '8483daea-f117-4e22-933c-55691075b516'	System	13 Oct 2020 23:51:36
User entered 'None (0)'	System	13 Oct 2020 23:51:36

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:15:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-13T19:51:18', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '8483daea-f117-4e22-933c-55691075b516'	System	13 Oct 2020 23:51:36
User entered 'None (0)'	System	13 Oct 2020 23:51:36

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:15:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-13T19:51:21', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '8483daea-f117-4e22-933c-55691075b516'	System	13 Oct 2020 23:51:36
User entered 'None (0)'	System	13 Oct 2020 23:51:36

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-13T19:51:24', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '8483daea-f117-4e22-933c-55691075b516'	System	13 Oct 2020 23:51:36
User entered 'No (N)'	System	13 Oct 2020 23:51:36

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:15:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-13T19:51:30', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '8483daea-f117-4e22-933c-55691075b516'	System	13 Oct 2020 23:51:36
User entered '13 Oct 2020 19:51'	System	13 Oct 2020 23:51:36

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '13 Oct 2020 12:00'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '14 Oct 2020 11:59'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
Data entry locked.	System	08 Oct 2020 18:47:36
User entered 'Day 7'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:15:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-14T18:04:01', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '4b761a00-c737-4694-aa2b-4acfd42ab464'	System	14 Oct 2020 22:04:24
User entered 'None (0)'	System	14 Oct 2020 22:04:24

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:15:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-14T18:04:04', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '4b761a00-c737-4694-aa2b-4acfd42ab464'	System	14 Oct 2020 22:04:24
User entered 'None (0)'	System	14 Oct 2020 22:04:24

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:15:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-14T18:04:06', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '4b761a00-c737-4694-aa2b-4acfd42ab464'	System	14 Oct 2020 22:04:24
User entered 'None (0)'	System	14 Oct 2020 22:04:24

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:15:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-14T18:04:08', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '4b761a00-c737-4694-aa2b-4acfd42ab464'	System	14 Oct 2020 22:04:24
User entered 'None (0)'	System	14 Oct 2020 22:04:24

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:15:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-14T18:04:10', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '4b761a00-c737-4694-aa2b-4acfd42ab464'	System	14 Oct 2020 22:04:24
User entered 'None (0)'	System	14 Oct 2020 22:04:24

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:15:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-14T18:04:12', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '4b761a00-c737-4694-aa2b-4acfd42ab464'	System	14 Oct 2020 22:04:24
User entered 'None (0)'	System	14 Oct 2020 22:04:24

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-14T18:04:15', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '4b761a00-c737-4694-aa2b-4acfd42ab464'	System	14 Oct 2020 22:04:24
User entered 'No (N)'	System	14 Oct 2020 22:04:24

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:15:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-10-14T18:04:19', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '4b761a00-c737-4694-aa2b-4acfd42ab464'	System	14 Oct 2020 22:04:24
User entered '14 Oct 2020 18:04'	System	14 Oct 2020 22:04:24

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:15:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '14 Oct 2020 12:00'	System	08 Oct 2020 18:47:36

US3352349

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:15:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
User entered '15 Oct 2020 11:59'	System	08 Oct 2020 18:47:36

US3352349

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:21:53
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:16:36
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4)	16 Oct 2020 13:37:50

US3352349

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:21:53
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:16:36
User entered '16 Oct 2020'	Yulexis Amestoy (b) (4)	16 Oct 2020 13:37:50

US3352349

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:21:53
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:16:36
User entered 'Contact Made (CONTACT MADE)'	Yulexis Amestoy (b) (4)	16 Oct 2020 13:37:50

US3352349

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:21:53
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:16:36
User entered empty.	Yulexis Amestoy (b) (4)	16 Oct 2020 13:37:50

US3352349

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:21:53
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:16:53
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4)	16 Oct 2020 13:37:54

US3352349

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:21:53
User entered 'I'	System	16 Oct 2020 13:37:54

US3352349

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:24
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:22:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Oct 2020 13:31:00

US3352349

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:24
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:22:55
User entered '23 Oct 2020'	(b) (4), (b) (6)	23 Oct 2020 13:31:00

US3352349

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:24
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:22:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	23 Oct 2020 13:31:00

US3352349

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:24
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:22:55
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 13:31:00

US3352349

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:24
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:23:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Oct 2020 13:31:04

US3352349

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:24
User entered 'I'	System	23 Oct 2020 13:31:04

US3352349

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:30:08
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:25:02
User entered 'Yes (Y)'	Sara Gomez (b) (4)	30 Oct 2020 18:23:23
	(b) (4)	

US3352349

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:30:08
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:25:02
User entered '30 Oct 2020'	Sara Gomez (b) (4)	30 Oct 2020 18:23:23
	(b) (4)	

US3352349

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:30:08
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:25:02
User entered 'Contact Made (CONTACT MADE)'	Sara Gomez (b) (4)	30 Oct 2020 18:23:23
	(b) (4)	

US3352349

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:30:08
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:25:02
User entered empty.	Sara Gomez (b) (4) (b) (4)	30 Oct 2020 18:23:23

US3352349

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:30:08
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:25:06
User entered 'Yes (Y)'	Sara Gomez (b) (4)	30 Oct 2020 18:23:27
	(b) (4)	

US3352349

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:30:08
User entered 'I'	System	30 Oct 2020 18:23:27

US3352349

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:15:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:54
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:38:24
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	03 Nov 2020 17:15:44

US3352349

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:54
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:38:24
User entered '3 Nov 2020'	Matthew Muniz (b) (4)	03 Nov 2020 17:15:44

US3352349

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:54
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:38:24
User entered 'Clinic (Clinic)'	Matthew Muniz (b) (4)	03 Nov 2020 17:15:44

US3352349

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:15:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:54
User entered 'VISIT3'	System	03 Nov 2020 17:15:44

US3352349

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:54
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:42:11
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	03 Nov 2020 17:16:15

US3352349

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:54
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:42:11
User entered '3 Nov 2020'	Matthew Muniz (b) (4)	03 Nov 2020 17:16:15

US3352349

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:54
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:42:11
User entered '11:07'	Matthew Muniz (b) (4)	03 Nov 2020 17:16:15

US3352349

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:54
User entered '3 Nov 2020 11:07'	System	03 Nov 2020 17:16:15

US3352349

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:54
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:42:11
User entered '36.9' C	Matthew Muniz (b) (4)	03 Nov 2020 17:16:15

US3352349

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:54
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:42:11
User entered 'Oral (Oral)'	Matthew Muniz (b) (4)	03 Nov 2020 17:16:15

US3352349

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:54
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:42:11
User entered empty.	Matthew Muniz (b) (4)	03 Nov 2020 17:16:15

US3352349

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:54
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:42:11
User entered '112'	Matthew Muniz (b) (4)	03 Nov 2020 17:16:15

US3352349

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:54
User entered 'bpm'	System	03 Nov 2020 17:16:15

US3352349

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:54
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:42:11
User entered '15'	Matthew Muniz (b) (4)	03 Nov 2020 17:16:15

US3352349

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:54
User entered 'breaths/min'	System	03 Nov 2020 17:16:15

US3352349

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:54
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:42:11
User entered '120'	Matthew Muniz (b) (4)	03 Nov 2020 17:16:15

US3352349

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:54
User entered 'mmHg'	System	03 Nov 2020 17:16:15

US3352349

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:54
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:42:11
User entered '86'	Matthew Muniz (b) (4)	03 Nov 2020 17:16:15

US3352349

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:54
User entered 'mmHg'	System	03 Nov 2020 17:16:15

US3352349

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:54

US3352349

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:54

US3352349

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:15:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:54
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:42:33
User entered 'No (N)'	Matthew Muniz (b) (4)	03 Nov 2020 17:16:20

US3352349

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:15:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:54
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:42:33
User entered empty.	Matthew Muniz (b) (4)	03 Nov 2020 17:16:20

US3352349

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:15:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:54
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:42:46
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sex (Male) recorded on this form does not match with the Sex (Female) reported in PPD Central lab. Please reconcile the correct Sex and update if confirmed. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 11:32:22
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sex (Male) recorded on this form does not match with the Sex (Female) reported in PPD Central lab. Please reconcile the correct Sex and update if confirmed. Else clarify, thank you.' answered with 'Subject is Male. PPD Central lab will be contacted to amend.' (Site from DM).	(b) (4), (b) (6)	14 Nov 2020 14:57:38
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sex (Male) recorded on this form does not match with the Sex (Female) reported in PPD Central lab. Please reconcile the correct Sex and update if confirmed. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 20:19:08
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	03 Nov 2020 17:16:34

US3352349

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:15:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:54
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:42:46
User entered '3 Nov 2020'	Matthew Muniz (b) (4)	03 Nov 2020 17:16:34

US3352349

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:54
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:42:46
User entered '11:27'	Matthew Muniz (b) (4)	03 Nov 2020 17:16:34

US3352349

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:54
User entered '3 Nov 2020 11:27'	System	03 Nov 2020 17:16:34

US3352349

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:54
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
User closed query 'Concomitant Medication log is blank in source and EDC. Please confirm with subject if they are were not taking any medication prior to enrolling. If not, please update the ConMed Summary Page to "No".' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 14:55:30
Query 'Concomitant Medication log is blank in source and EDC. Please confirm with subject if they are were not taking any medication prior to enrolling. If not, please update the ConMed Summary Page to "No".' answered with 'UPDATED' (Site from CRA).	Matthew Muniz (b) (4)	19 Jan 2021 14:44:48
User opened query 'Concomitant Medication log is blank in source and EDC. Please confirm with subject if they are were not taking any medication prior to enrolling. If not, please update the ConMed Summary Page to "No".' (Site from CRA).	(b) (4), (b) (6)	14 Dec 2020 19:50:17
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 19:43:14
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	03 Nov 2020 17:15:22

US3352349

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:54
User entered 'I'	System	03 Nov 2020 17:15:22

US3352349

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
Data entry locked.	System	10 Sep 2020 19:45:21
User entered 'Day 64'	System	10 Sep 2020 19:45:21

US3352349

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-11-10T00:01:25', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '08c405e3-1c1f-40c5-aa42-88cec75a8f1e'	System	10 Nov 2020 05:01:51
User entered 'No (N)'	System	10 Nov 2020 05:01:51

US3352349

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-11-10T00:01:30', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '08c405e3-1c1f-40c5-aa42-88cec75a8f1e'	System	10 Nov 2020 05:01:51
User entered 'No (N)'	System	10 Nov 2020 05:01:51

US3352349

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-11-10T00:01:46', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '08c405e3-1c1f-40c5-aa42-88cec75a8f1e'	System	10 Nov 2020 05:01:51
User entered '10 Nov 2020 00:01:46'	System	10 Nov 2020 05:01:51

US3352349

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
Data entry locked.	System	10 Sep 2020 19:45:21
User entered '10 Nov 2020 00:01'	System	10 Sep 2020 19:45:21

US3352349

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
Data entry locked.	System	10 Sep 2020 19:45:21
User entered '14 Nov 2020 23:59'	System	10 Sep 2020 19:45:21

US3352349

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
Data entry locked.	System	10 Sep 2020 19:45:21
User entered 'Day 71'	System	10 Sep 2020 19:45:21

US3352349

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-11-17T04:00:01', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '489c7ac0-3e54-4c05-b0f7-107c73a678e9'	System	17 Nov 2020 09:00:15
User entered 'No (N)'	System	17 Nov 2020 09:00:15

US3352349

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-11-17T04:00:06', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '489c7ac0-3e54-4c05-b0f7-107c73a678e9'	System	17 Nov 2020 09:00:15
User entered 'No (N)'	System	17 Nov 2020 09:00:15

US3352349

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-11-17T04:00:10', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '489c7ac0-3e54-4c05-b0f7-107c73a678e9'	System	17 Nov 2020 09:00:15
User entered '17 Nov 2020 04:00:10'	System	17 Nov 2020 09:00:15

US3352349

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
Data entry locked.	System	10 Sep 2020 19:45:21
User entered '17 Nov 2020 00:01'	System	10 Sep 2020 19:45:21

US3352349

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:46:37
Data entry locked.	System	10 Sep 2020 19:45:21
User entered '21 Nov 2020 23:59'	System	10 Sep 2020 19:45:21

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[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 (3c5f25052dcd7366)', Time: '2020-11-25T08:39:00', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'e2ae959e-d76d-4d20-8f14-4f34cb368aae'	System	25 Nov 2020 13:39:15
User entered 'No (N)'	System	25 Nov 2020 13:39:15

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Have you been exposed to someone with 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 (3c5f25052dcd7366)', Time: '2020-11-25T08:39:05', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'e2ae959e-d76d-4d20-8f14-4f34cb368aae'	System	25 Nov 2020 13:39:15
User entered 'No (N)'	System	25 Nov 2020 13:39:15

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-11-25T08:39:13', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'e2ae959e-d76d-4d20-8f14-4f34cb368aae'	System	25 Nov 2020 13:39:15
User entered '25 Nov 2020 08:39:13'	System	25 Nov 2020 13:39:15

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[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 (3c5f25052dcd7366)', Time: '2020-11-28T19:15:57', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '585107d1-472f-447f-8966-6da5fc8c9958'	System	29 Nov 2020 00:16:06
User entered 'No (N)'	System	29 Nov 2020 00:16:06

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Have you been exposed to someone with 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 (3c5f25052dcd7366)', Time: '2020-11-28T19:16:00', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '585107d1-472f-447f-8966-6da5fc8c9958'	System	29 Nov 2020 00:16:06
User entered 'No (N)'	System	29 Nov 2020 00:16:06

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-11-28T19:16:03', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '585107d1-472f-447f-8966-6da5fc8c9958'	System	29 Nov 2020 00:16:06
User entered '28 Nov 2020 19:16:03'	System	29 Nov 2020 00:16:06

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[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 (3c5f25052dcd7366)', Time: '2020-12-05T06:52:14', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '110eabfb-fedf-4ad3-84b3-1b80805a39a5'	System	05 Dec 2020 11:52:24
User entered 'No (N)'	System	05 Dec 2020 11:52:24

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Have you been exposed to someone with 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 (3c5f25052dcd7366)', Time: '2020-12-05T06:52:19', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '110eabfb-fedf-4ad3-84b3-1b80805a39a5'	System	05 Dec 2020 11:52:24
User entered 'No (N)'	System	05 Dec 2020 11:52:24

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-12-05T06:52:22', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '110eabfb-fedf-4ad3-84b3-1b80805a39a5'	System	05 Dec 2020 11:52:24
User entered '05 Dec 2020 06:52:22'	System	05 Dec 2020 11:52:24

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[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 (3c5f25052dcd7366)', Time: '2020-12-12T10:18:28', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '8a689056-c4ea-4053-8dfc-36ca6a0e6579'	System	12 Dec 2020 15:18:42
User entered 'No (N)'	System	12 Dec 2020 15:18:42

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Have you been exposed to someone with 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 (3c5f25052dcd7366)', Time: '2020-12-12T10:18:33', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '8a689056-c4ea-4053-8dfc-36ca6a0e6579'	System	12 Dec 2020 15:18:42
User entered 'No (N)'	System	12 Dec 2020 15:18:42

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-12-12T10:18:38', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '8a689056-c4ea-4053-8dfc-36ca6a0e6579'	System	12 Dec 2020 15:18:42
User entered '12 Dec 2020 10:18:38'	System	12 Dec 2020 15:18:42

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[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 (3c5f25052dcd7366)', Time: '2020-12-21T18:16:22', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'b9983d78-9b87-4f05-8f82-f34b71e477c0'	System	21 Dec 2020 23:16:30
User entered 'No (N)'	System	21 Dec 2020 23:16:30

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Have you been exposed to someone with 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 (3c5f25052dcd7366)', Time: '2020-12-21T18:16:25', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'b9983d78-9b87-4f05-8f82-f34b71e477c0'	System	21 Dec 2020 23:16:30
User entered 'No (N)'	System	21 Dec 2020 23:16:30

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-12-21T18:16:28', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'b9983d78-9b87-4f05-8f82-f34b71e477c0'	System	21 Dec 2020 23:16:30
User entered '21 Dec 2020 18:16:28'	System	21 Dec 2020 23:16:30

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[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 (3c5f25052dcd7366)', Time: '2020-12-27T17:45:43', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'f4bd051b-7fc5-4f35-a765-5fc0f8f96492'	System	27 Dec 2020 22:45:55
User entered 'No (N)'	System	27 Dec 2020 22:45:55

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Have you been exposed to someone with 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 (3c5f25052dcd7366)', Time: '2020-12-27T17:45:45', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'f4bd051b-7fc5-4f35-a765-5fc0f8f96492'	System	27 Dec 2020 22:45:55
User entered 'No (N)'	System	27 Dec 2020 22:45:55

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2020-12-27T17:45:52', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'f4bd051b-7fc5-4f35-a765-5fc0f8f96492' User entered '27 Dec 2020 17:45:52'	System	27 Dec 2020 22:45:55
	System	27 Dec 2020 22:45:55

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[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 (3c5f25052dcd7366)', Time: '2021-01-03T10:45:03', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'c50476fa-1de5-4a74-a062-64d0b88e66ec'	System	03 Jan 2021 15:45:11
User entered 'No (N)'	System	03 Jan 2021 15:45:11

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Have you been exposed to someone with 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 (3c5f25052dcd7366)', Time: '2021-01-03T10:45:05', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'c50476fa-1de5-4a74-a062-64d0b88e66ec'	System	03 Jan 2021 15:45:11
User entered 'No (N)'	System	03 Jan 2021 15:45:11

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2021-01-03T10:45:09', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'c50476fa-1de5-4a74-a062-64d0b88e66ec'	System	03 Jan 2021 15:45:11
User entered '03 Jan 2021 10:45:09'	System	03 Jan 2021 15:45:11

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[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 (3c5f25052dcd7366)', Time: '2021-01-11T14:12:48', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '5215f5c1-99e4-49e2-a771-788e4172ad61'	System	11 Jan 2021 19:12:55
User entered 'No (N)'	System	11 Jan 2021 19:12:55

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Have you been exposed to someone with 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 (3c5f25052dcd7366)', Time: '2021-01-11T14:12:50', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '5215f5c1-99e4-49e2-a771-788e4172ad61'	System	11 Jan 2021 19:12:55
User entered 'No (N)'	System	11 Jan 2021 19:12:55

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2021-01-11T14:12:52', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '5215f5c1-99e4-49e2-a771-788e4172ad61' User entered '11 Jan 2021 14:12:52'	System	11 Jan 2021 19:12:55
	System	11 Jan 2021 19:12:55

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[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 (3c5f25052dcd7366)', Time: '2021-01-18T21:34:14', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'cfb8e92b-8687-420d-8bc1-8c8e12eb227d'	System	19 Jan 2021 02:34:22
User entered 'No (N)'	System	19 Jan 2021 02:34:22

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Have you been exposed to someone with 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 (3c5f25052dcd7366)', Time: '2021-01-18T21:34:17', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'cfb8e92b-8687-420d-8bc1-8c8e12eb227d'	System	19 Jan 2021 02:34:22
User entered 'No (N)'	System	19 Jan 2021 02:34:22

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2021-01-18T21:34:21', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'cfb8e92b-8687-420d-8bc1-8c8e12eb227d'	System	19 Jan 2021 02:34:22
User entered '18 Jan 2021 21:34:21'	System	19 Jan 2021 02:34:22

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[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 (3c5f25052dcd7366)', Time: '2021-01-23T08:03:44', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '16a3797a-22e3-4bef-a0a0-85176cc683d0'	System	23 Jan 2021 13:03:56
User entered 'No (N)'	System	23 Jan 2021 13:03:56

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Have you been exposed to someone with 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 (3c5f25052dcd7366)', Time: '2021-01-23T08:03:49', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '16a3797a-22e3-4bef-a0a0-85176cc683d0'	System	23 Jan 2021 13:03:56
User entered 'No (N)'	System	23 Jan 2021 13:03:56

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2021-01-23T08:03:51', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '16a3797a-22e3-4bef-a0a0-85176cc683d0'	System	23 Jan 2021 13:03:56
User entered '23 Jan 2021 08:03:51'	System	23 Jan 2021 13:03:56

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[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 (3c5f25052dcd7366)', Time: '2021-01-31T11:33:52', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'c661d36a-9acf-4c82-8466-31f8201b38ec'	System	31 Jan 2021 16:33:59
User entered 'No (N)'	System	31 Jan 2021 16:33:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Have you been exposed to someone with 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 (3c5f25052dcd7366)', Time: '2021-01-31T11:33:54', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'c661d36a-9acf-4c82-8466-31f8201b38ec'	System	31 Jan 2021 16:33:59
User entered 'No (N)'	System	31 Jan 2021 16:33:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2021-01-31T11:33:57', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'c661d36a-9acf-4c82-8466-31f8201b38ec' User entered '31 Jan 2021 11:33:57'	System	31 Jan 2021 16:33:59
	System	31 Jan 2021 16:33:59

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[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 (3c5f25052dcd7366)', Time: '2021-02-06T02:49:01', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '36930416-cc2a-4a36-85b3-e375ef6d0f99'	System	06 Feb 2021 07:49:07
User entered 'No (N)'	System	06 Feb 2021 07:49:07

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Have you been exposed to someone with 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 (3c5f25052dcd7366)', Time: '2021-02-06T02:49:03', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '36930416-cc2a-4a36-85b3-e375ef6d0f99'	System	06 Feb 2021 07:49:07
User entered 'No (N)'	System	06 Feb 2021 07:49:07

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2021-02-06T02:49:06', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '36930416-cc2a-4a36-85b3-e375ef6d0f99'	System	06 Feb 2021 07:49:07
User entered '06 Feb 2021 02:49:06'	System	06 Feb 2021 07:49:07

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[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 (3c5f25052dcd7366)', Time: '2021-02-16T03:57:29', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'eefa0ceb-7b97-47db-85a1-9a23aa6fac71'	System	16 Feb 2021 08:57:38
User entered 'No (N)'	System	16 Feb 2021 08:57:38

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Have you been exposed to someone with 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 (3c5f25052dcd7366)', Time: '2021-02-16T03:57:31', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'eefa0ceb-7b97-47db-85a1-9a23aa6fac71'	System	16 Feb 2021 08:57:38
User entered 'No (N)'	System	16 Feb 2021 08:57:38

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2021-02-16T03:57:34', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'eefa0ceb-7b97-47db-85a1-9a23aa6fac71' User entered '16 Feb 2021 03:57:34'	System	16 Feb 2021 08:57:38
	System	16 Feb 2021 08:57:38

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[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 (3c5f25052dcd7366)', Time: '2021-02-20T12:13:16', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'b536bc6f-dc19-4438-bb2b-689288dce19c'	System	20 Feb 2021 17:16:08
User entered 'No (N)'	System	20 Feb 2021 17:16:08

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Have you been exposed to someone with 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 (3c5f25052dcd7366)', Time: '2021-02-20T12:13:18', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'b536bc6f-dc19-4438-bb2b-689288dce19c'	System	20 Feb 2021 17:16:08
User entered 'No (N)'	System	20 Feb 2021 17:16:08

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3c5f25052dcd7366)', Time: '2021-02-20T12:13:25', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'b536bc6f-dc19-4438-bb2b-689288dce19c' User entered '20 Feb 2021 12:13:25'	System	20 Feb 2021 17:16:08

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[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 (31f529d33cefd1a9)', Time: '2021-04-07T22:14:34-04:00', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'd40e5735-340f-424f-96a6-9078f280c5eb'	System	08 Apr 2021 02:16:44
User entered 'Yes (Y)'	System	08 Apr 2021 02:16:44

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Have you been exposed to someone with 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 (31f529d33cefd1a9)', Time: '2021-04-07T22:14:45-04:00', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'd40e5735-340f-424f-96a6-9078f280c5eb'	System	08 Apr 2021 02:16:44
User entered 'No (N)'	System	08 Apr 2021 02:16:44

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31f529d33cefd1a9)', Time: '2021-04-07T22:15:06-04:00', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'd40e5735-340f-424f-96a6-9078f280c5eb'	System	08 Apr 2021 02:16:44
User entered 'Yes (Y)'	System	08 Apr 2021 02:16:44

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31f529d33cefd1a9)', Time: '2021-04-07T22:15:41-04:00', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'd40e5735-340f-424f-96a6-9078f280c5eb' User entered '1'	System	08 Apr 2021 02:16:44

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31f529d33cefd1a9)', Time: '2021-04-07T22:15:41-04:00', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'd40e5735-340f-424f-96a6-9078f280c5eb' User entered '0'	System	08 Apr 2021 02:16:44
	System	08 Apr 2021 02:16:44

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31f529d33cefd1a9)', Time: '2021-04-07T22:15:41-04:00', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'd40e5735-340f-424f-96a6-9078f280c5eb'	System	08 Apr 2021 02:16:44
User entered '1'	System	08 Apr 2021 02:16:44

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31f529d33cefd1a9)', Time: '2021-04-07T22:15:41-04:00', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'd40e5735-340f-424f-96a6-9078f280c5eb' User entered '0'	System	08 Apr 2021 02:16:44
	System	08 Apr 2021 02:16:44

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31f529d33cefd1a9)', Time: '2021-04-07T22:15:41-04:00', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'd40e5735-340f-424f-96a6-9078f280c5eb' User entered '0'	System	08 Apr 2021 02:16:44
	System	08 Apr 2021 02:16:44

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31f529d33cefd1a9)', Time: '2021-04-07T22:15:41-04:00', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'd40e5735-340f-424f-96a6-9078f280c5eb' User entered '0'	System	08 Apr 2021 02:16:44
	System	08 Apr 2021 02:16:44

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31f529d33cefd1a9)', Time: '2021-04-07T22:15:41-04:00', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'd40e5735-340f-424f-96a6-9078f280c5eb' User entered '0'	System	08 Apr 2021 02:16:44
	System	08 Apr 2021 02:16:44

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31f529d33cefd1a9)', Time: '2021-04-07T22:15:41-04:00', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'd40e5735-340f-424f-96a6-9078f280c5eb' User entered '0'	System	08 Apr 2021 02:16:44
	System	08 Apr 2021 02:16:44

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31f529d33cefd1a9)', Time: '2021-04-07T22:15:41-04:00', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'd40e5735-340f-424f-96a6-9078f280c5eb' User entered '0'	System	08 Apr 2021 02:16:44
	System	08 Apr 2021 02:16:44

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31f529d33cefd1a9)', Time: '2021-04-07T22:15:41-04:00', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'd40e5735-340f-424f-96a6-9078f280c5eb' User entered '0'	System	08 Apr 2021 02:16:44

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31f529d33cefd1a9)', Time: '2021-04-07T22:15:41-04:00', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'd40e5735-340f-424f-96a6-9078f280c5eb' User entered '0'	System	08 Apr 2021 02:16:44
	System	08 Apr 2021 02:16:44

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31f529d33cefd1a9)', Time: '2021-04-07T22:15:41-04:00', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'd40e5735-340f-424f-96a6-9078f280c5eb' User entered '0'	System	08 Apr 2021 02:16:44
	System	08 Apr 2021 02:16:44

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31f529d33cefd1a9)', Time: '2021-04-07T22:15:41-04:00', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'd40e5735-340f-424f-96a6-9078f280c5eb' User entered '0'	System	08 Apr 2021 02:16:44
	System	08 Apr 2021 02:16:44

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31f529d33cefd1a9)', Time: '2021-04-07T22:15:41-04:00', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'd40e5735-340f-424f-96a6-9078f280c5eb' User entered '0'	System	08 Apr 2021 02:16:44
	System	08 Apr 2021 02:16:44

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31f529d33cefd1a9)', Time: '2021-04-07T22:15:41-04:00', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'd40e5735-340f-424f-96a6-9078f280c5eb' User entered '0'	System	08 Apr 2021 02:16:44
	System	08 Apr 2021 02:16:44

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31f529d33cefd1a9)', Time: '2021-04-07T22:15:41-04:00', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'd40e5735-340f-424f-96a6-9078f280c5eb' User entered '0'	System	08 Apr 2021 02:16:44
	System	08 Apr 2021 02:16:44

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31f529d33cefd1a9)', Time: '2021-04-07T22:15:41-04:00', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'd40e5735-340f-424f-96a6-9078f280c5eb' User entered '0'	System	08 Apr 2021 02:16:44
	System	08 Apr 2021 02:16:44

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31f529d33cefd1a9)', Time: '2021-04-07T22:15:47-04:00', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'd40e5735-340f-424f-96a6-9078f280c5eb'	System	08 Apr 2021 02:16:44
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	08 Apr 2021 02:16:44

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31f529d33cefd1a9)', Time: '2021-04-07T22:16:07-04:00', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'd40e5735-340f-424f-96a6-9078f280c5eb'	System	08 Apr 2021 02:16:44
User entered 'Yes (Y)'	System	08 Apr 2021 02:16:44

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31f529d33cefd1a9)', Time: '2021-04-07T22:16:10-04:00', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'd40e5735-340f-424f-96a6-9078f280c5eb'	System	08 Apr 2021 02:16:44
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	08 Apr 2021 02:16:44

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31f529d33cefd1a9)', Time: '2021-04-07T22:16:15-04:00', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'd40e5735-340f-424f-96a6-9078f280c5eb' User entered '07 Apr 2021 22:16:15'	System	08 Apr 2021 02:16:44
	System	08 Apr 2021 02:16:44

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[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 (31f529d33cefd1a9)', Time: '2021-04-10T09:36:18-04:00', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '1030fa95-8719-45d3-a146-9e309c6fbc7d'	System	10 Apr 2021 13:36:28
User entered 'No (N)'	System	10 Apr 2021 13:36:28

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Have you been exposed to someone with 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 (31f529d33cefd1a9)', Time: '2021-04-10T09:36:21-04:00', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '1030fa95-8719-45d3-a146-9e309c6fbc7d'	System	10 Apr 2021 13:36:28
User entered 'No (N)'	System	10 Apr 2021 13:36:28

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31f529d33cefd1a9)', Time: '2021-04-10T09:36:25-04:00', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '1030fa95-8719-45d3-a146-9e309c6fbc7d'	System	10 Apr 2021 13:36:28
User entered '10 Apr 2021 09:36:25'	System	10 Apr 2021 13:36:28

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[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 (31f529d33cefd1a9)', Time: '2021-04-17T21:47:01-04:00', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'a998423a-8134-4a1b-8fca-7093fc3d8aff'	System	18 Apr 2021 01:47:09
User entered 'No (N)'	System	18 Apr 2021 01:47:09

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Have you been exposed to someone with 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 (31f529d33cefd1a9)', Time: '2021-04-17T21:47:03-04:00', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'a998423a-8134-4a1b-8fca-7093fc3d8aff' User entered 'No (N)'	System	18 Apr 2021 01:47:09

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31f529d33cefd1a9)', Time: '2021-04-17T21:47:06-04:00', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'a998423a-8134-4a1b-8fca-7093fc3d8aff' User entered '17 Apr 2021 21:47:06'	System	18 Apr 2021 01:47:09
	System	18 Apr 2021 01:47:09

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[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 (31f529d33cefd1a9)', Time: '2021-04-24T02:25:45-04:00', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'bc1d9e59-8ae0-4bc5-9e79-cf0f256b04a6'	System	24 Apr 2021 06:25:55
User entered 'No (N)'	System	24 Apr 2021 06:25:55

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Have you been exposed to someone with 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 (31f529d33cefd1a9)', Time: '2021-04-24T02:25:47-04:00', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'bc1d9e59-8ae0-4bc5-9e79-cf0f256b04a6'	System	24 Apr 2021 06:25:55
User entered 'No (N)'	System	24 Apr 2021 06:25:55

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31f529d33cefd1a9)', Time: '2021-04-24T02:25:51-04:00', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: 'bc1d9e59-8ae0-4bc5-9e79-cf0f256b04a6'	System	24 Apr 2021 06:25:55
User entered '24 Apr 2021 02:25:51'	System	24 Apr 2021 06:25:55

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[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 (31f529d33cefd1a9)', Time: '2021-05-03T08:49:42-04:00', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '0b5eb004-bcaf-41b0-a542-41527c13d505'	System	03 May 2021 12:49:52
User entered 'No (N)'	System	03 May 2021 12:49:52

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

Have you been exposed to someone with 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 (31f529d33cefd1a9)', Time: '2021-05-03T08:49:45-04:00', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '0b5eb004-bcaf-41b0-a542-41527c13d505'	System	03 May 2021 12:49:52
User entered 'No (N)'	System	03 May 2021 12:49:52

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31f529d33cefd1a9)', Time: '2021-05-03T08:49:48-04:00', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '0b5eb004-bcaf-41b0-a542-41527c13d505'	System	03 May 2021 12:49:52
User entered '03 May 2021 08:49:48'	System	03 May 2021 12:49:52

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '12 Nov 2022 00:01'	System	20 Nov 2020 07:16:48

US3352349

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:48
Amendment Manager: User entered '16 Nov 2022 23:59'	System	20 Nov 2020 07:16:48

US3352349

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:15:59

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)	26 Apr 2021 05:39:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31f529d33cefd1a9)', Time: '2021-04-09T05:02:52-04:00', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '1baa5fa2-e556-4c2c-a03e-e1630442eb81'	System	09 Apr 2021 09:03:00
User entered 'No (N)'	System	09 Apr 2021 09:03:00

US3352349

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:15:59

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:39:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (31f529d33cefd1a9)', Time: '2021-04-09T05:02:55-04:00', User OID: 'PatientReportedOutcome (US3352349)', ODM File OID: '1baa5fa2-e556-4c2c-a03e-e1630442eb81' User entered '09 Apr 2021 05:02:55'	System	09 Apr 2021 09:03:00
	System	09 Apr 2021 09:03:00

US3352349

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:27
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:25:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Dec 2020 20:23:27

US3352349

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:27
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:25:24
User entered '2 Dec 2020'	(b) (4), (b) (6)	02 Dec 2020 20:23:27

US3352349

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:27
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:25:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	02 Dec 2020 20:23:27

US3352349

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:27
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:25:24
User entered empty.	(b) (4), (b) (6)	02 Dec 2020 20:23:27

US3352349

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:27
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:25:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Dec 2020 20:23:31

US3352349

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:41:27
User entered 'I'	System	02 Dec 2020 20:23:31

US3352349

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:38:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:28:37
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4)	08 Jan 2021 15:53:53

US3352349

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:38:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:28:37
User entered '8 Jan 2021'	Yulexis Amestoy (b) (4)	08 Jan 2021 15:53:53

US3352349

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:38:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:28:37
User entered 'Contact Made (CONTACT MADE)'	Yulexis Amestoy (b) (4)	08 Jan 2021 15:53:53

US3352349

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:38:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:28:37
User entered empty.	Yulexis Amestoy (b) (4)	08 Jan 2021 15:53:53

US3352349

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:38:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:28:44
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4)	08 Jan 2021 15:53:58

US3352349

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:38:13
User entered 'I'	System	08 Jan 2021 15:53:58

US3352349

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:38:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:30:45
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4)	03 Feb 2021 17:26:10

US3352349

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:38:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:30:45
User entered '3 Feb 2021'	Yulexis Amestoy (b) (4)	03 Feb 2021 17:26:10

US3352349

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:38:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:30:45
User entered 'Contact Made (CONTACT MADE)'	Yulexis Amestoy (b) (4)	03 Feb 2021 17:26:10

US3352349

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:38:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:30:45
User entered empty.	Yulexis Amestoy (b) (4)	03 Feb 2021 17:26:10

US3352349

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:38:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:32:03
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4)	03 Feb 2021 17:26:03

US3352349

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:38:13
User entered 'I'	System	03 Feb 2021 17:26:03

US3352349

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:38:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:36:44
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4)	10 Mar 2021 18:04:52

US3352349

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:38:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:36:44
User entered '8 Mar 2021'	Yulexis Amestoy (b) (4)	10 Mar 2021 18:04:52

US3352349

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:38:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:36:44
User entered 'Contact Not Made (CONTACT NOT MADE)'	Yulexis Amestoy (b) (4)	10 Mar 2021 18:04:52

US3352349

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:38:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:36:44
User entered '3 ATTEMPTS MADE. UNABLE TO REACH.'	Yulexis Amestoy (b) (4)	10 Mar 2021 18:04:52

US3352349

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:38:13
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:36:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Mar 2021 15:17:57

US3352349

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:38:13
User entered 'I'	System	30 Mar 2021 15:17:57

US3352349

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:15:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	26 Apr 2021 21:30:06

US3352349

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:15:59

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	29 Apr 2021 06:30:02
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
Query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'Visit was completed 6 days out of window due to subject being in the hospital. Protocol deviation documented.' (Site from System).	(b) (4), (b) (6)	27 Apr 2021 20:08:50
User opened query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	26 Apr 2021 21:30:06
User entered '26 Apr 2021'	Matthew Muniz (b) (4)	26 Apr 2021 21:30:06

US3352349

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
User entered 'Clinic (Clinic)'	Matthew Muniz (b) (4)	26 Apr 2021 21:30:06

US3352349

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:15:59

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	26 Apr 2021 21:30:06

US3352349

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	26 Apr 2021 21:30:58

US3352349

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
User entered '26 Apr 2021'	Matthew Muniz (b) (4)	26 Apr 2021 21:30:58

US3352349

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
User entered '10:13'	Matthew Muniz (b) (4)	26 Apr 2021 21:30:58

US3352349

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
User entered '26 Apr 2021 10:13'	System	26 Apr 2021 21:30:58

US3352349

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
User entered '37.1' C	Matthew Muniz (b) (4)	26 Apr 2021 21:30:58

US3352349

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
User entered 'Oral (Oral)'	Matthew Muniz (b) (4)	26 Apr 2021 21:30:58

US3352349

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
User entered empty.	Matthew Muniz (b) (4)	26 Apr 2021 21:30:58

US3352349

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
User entered '94'	Matthew Muniz (b) (4)	26 Apr 2021 21:30:58

US3352349

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	26 Apr 2021 21:30:58

US3352349

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
User entered '13'	Matthew Muniz (b) (4)	26 Apr 2021 21:30:58

US3352349

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	26 Apr 2021 21:30:58

US3352349

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
User entered '132'	Matthew Muniz (b) (4)	26 Apr 2021 21:30:58

US3352349

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	26 Apr 2021 21:30:58

US3352349

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
User entered '88'	Matthew Muniz (b) (4)	26 Apr 2021 21:30:58

US3352349

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	26 Apr 2021 21:30:58

US3352349

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:15:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
User entered 'No (N)'	Matthew Muniz (b) (4)	26 Apr 2021 21:31:23

US3352349

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:15:59

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
User entered empty.	Matthew Muniz (b) (4)	26 Apr 2021 21:31:23

US3352349

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:15:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	26 Apr 2021 21:31:43

US3352349

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:15:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
User entered '26 Apr 2021'	Matthew Muniz (b) (4)	26 Apr 2021 21:31:43

US3352349

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
User entered '10:43'	Matthew Muniz (b) (4)	26 Apr 2021 21:31:43

US3352349

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
User entered '26 Apr 2021 10:43'	System	26 Apr 2021 21:31:43

US3352349

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:04:25
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	26 Apr 2021 21:31:49

US3352349

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Apr 2021 21:31:49

US3352349

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

Form: Visit Date

Generated On: 09 Jun 2021 17:15:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:57:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Feb 2021 18:02:47

US3352349

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

Form: Visit Date

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:57:10
User entered '03 Feb 2021'	(b) (4), (b) (6)	03 Feb 2021 18:02:47

US3352349

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

Form: Visit Date

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:57:10
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	03 Feb 2021 18:02:47

US3352349

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

Form: Visit Date

Generated On: 09 Jun 2021 17:15:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User entered 'UNBLND_DECIDE'	System	03 Feb 2021 18:02:47

US3352349

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

Form: Unblinding

Generated On: 09 Jun 2021 17:15:59

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:57:35
User entered '03 Feb 2021'	(b) (4), (b) (6)	03 Feb 2021 18:03:42

US3352349

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

Form: Unblinding

Generated On: 09 Jun 2021 17:15:59

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 19:06:59

US3352349

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

Form: Unblinding

Generated On: 09 Jun 2021 17:15:59

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:57:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Feb 2021 18:03:42

US3352349

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

Form: Unblinding

Generated On: 09 Jun 2021 17:15:59

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 19:06:59

US3352349

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

Form: Unblinding

Generated On: 09 Jun 2021 17:15:59

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:57:35
User entered '03 Feb 2021'	(b) (4), (b) (6)	03 Feb 2021 18:03:42

US3352349

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

Form: Unblinding

Generated On: 09 Jun 2021 17:15:59

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:57:35
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	03 Feb 2021 18:03:42

US3352349

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

Form: Unblinding

Generated On: 09 Jun 2021 17:15:59

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:57:35
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	03 Feb 2021 18:03:42

US3352349

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

Form: Unblinding

Generated On: 09 Jun 2021 17:15:59

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:57:35
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	03 Feb 2021 18:03:42

US3352349

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

Form: Unblinding

Generated On: 09 Jun 2021 17:15:59

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:57:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Feb 2021 18:03:42

US3352349

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

Form: Unblinding

Generated On: 09 Jun 2021 17:15:59

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User entered 'I'	System	03 Feb 2021 18:03:42

US3352349

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

Form: Unblinding

Generated On: 09 Jun 2021 17:15:59

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User entered 'I'	System	03 Feb 2021 18:03:42

US3352349

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:15:59

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:58:50
User entered empty.	(b) (4), (b) (6)	03 Feb 2021 18:08:43

US3352349

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:15:59

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:58:50
User entered empty.	(b) (4), (b) (6)	03 Feb 2021 18:08:43

US3352349

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:15:59

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User entered empty.	System	03 Feb 2021 18:08:43
DataPoint set to visible.	System	03 Feb 2021 18:03:42

US3352349

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:15:59

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:58:50
User entered empty.	(b) (4), (b) (6)	03 Feb 2021 18:08:43

US3352349

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:15:59

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:58:50
User entered empty.	(b) (4), (b) (6)	03 Feb 2021 18:08:43

US3352349

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:15:59

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User entered empty.	System	03 Feb 2021 18:08:43
DataPoint set to visible.	System	03 Feb 2021 18:03:42

US3352349

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	03 Feb 2021 18:08:43

US3352349

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:58:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Feb 2021 18:08:43

US3352349

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:58:50
User entered '03 Feb 2021'	(b) (4), (b) (6)	03 Feb 2021 18:08:43

US3352349

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:58:50
User entered '10:17'	(b) (4), (b) (6)	03 Feb 2021 18:08:43

US3352349

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User entered '03 Feb 2021 10:17'	System	03 Feb 2021 18:08:43

US3352349

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:58:50
User entered '37.2' C	(b) (4), (b) (6)	03 Feb 2021 18:08:43

US3352349

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:58:50
User entered 'Oral (Oral)'	(b) (4), (b) (6)	03 Feb 2021 18:08:43

US3352349

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:58:50
User entered empty.	(b) (4), (b) (6)	03 Feb 2021 18:08:43

US3352349

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:58:50
User entered '67'	(b) (4), (b) (6)	03 Feb 2021 18:08:43

US3352349

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User entered 'bpm'	System	03 Feb 2021 18:08:43

US3352349

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:58:50
User entered '15'	(b) (4), (b) (6)	03 Feb 2021 18:08:43

US3352349

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User entered 'breaths/min'	System	03 Feb 2021 18:08:43

US3352349

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:58:50
User entered '139'	(b) (4), (b) (6)	03 Feb 2021 18:08:43

US3352349

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User entered 'mmHg'	System	03 Feb 2021 18:08:43

US3352349

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:58:50
User entered '88'	(b) (4), (b) (6)	03 Feb 2021 18:08:43

US3352349

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User entered 'mmHg'	System	03 Feb 2021 18:08:43

US3352349

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:15:59

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:58:50
User entered empty.	(b) (4), (b) (6)	03 Feb 2021 18:08:43

US3352349

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:15:59

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:58:50
User entered empty.	(b) (4), (b) (6)	03 Feb 2021 18:08:43

US3352349

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User entered empty.	System	03 Feb 2021 18:08:43
DataPoint set to visible.	System	03 Feb 2021 18:03:42

US3352349

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	03 Feb 2021 18:08:43

US3352349

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:58:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Feb 2021 18:08:43

US3352349

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:58:50
User entered '03 Feb 2021'	(b) (4), (b) (6)	03 Feb 2021 18:08:43

US3352349

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:58:50
User entered '11:38'	(b) (4), (b) (6)	03 Feb 2021 18:08:43

US3352349

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User entered '03 Feb 2021 11:38'	System	03 Feb 2021 18:08:43

US3352349

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:58:50
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	08 Feb 2021 20:33:21
User entered '37.3' C reason for change: Data Entry Error	(b) (4), (b) (6)	08 Feb 2021 20:33:21
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	03 Feb 2021 18:08:43
User entered '37.3' (non-conformant).	(b) (4), (b) (6)	03 Feb 2021 18:08:43

US3352349

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:58:50
User entered 'Oral (Oral)'	(b) (4), (b) (6)	03 Feb 2021 18:08:43

US3352349

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:58:50
User entered empty.	(b) (4), (b) (6)	03 Feb 2021 18:08:43

US3352349

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:58:50
User entered '100'	(b) (4), (b) (6)	03 Feb 2021 18:08:43

US3352349

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User entered 'bpm'	System	03 Feb 2021 18:08:43

US3352349

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:58:50
User entered '16'	(b) (4), (b) (6)	03 Feb 2021 18:08:43

US3352349

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User entered 'breaths/min'	System	03 Feb 2021 18:08:43

US3352349

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:58:50
User entered '130'	(b) (4), (b) (6)	03 Feb 2021 18:08:43

US3352349

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User entered 'mmHg'	System	03 Feb 2021 18:08:43

US3352349

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:58:50
User entered '79'	(b) (4), (b) (6)	03 Feb 2021 18:08:43

US3352349

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User entered 'mmHg'	System	03 Feb 2021 18:08:43

US3352349

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:15:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:59:06
User entered 'No (N)'	(b) (4), (b) (6)	03 Feb 2021 18:09:00

US3352349

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:15:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:59:06
User entered empty.	(b) (4), (b) (6)	03 Feb 2021 18:09:00

US3352349

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

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:59:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Feb 2021 18:10:20

US3352349

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

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:59:29
User entered empty.	(b) (4), (b) (6)	03 Feb 2021 18:10:20

US3352349

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

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

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)	29 Apr 2021 15:50:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:59:29
User entered empty.	(b) (4), (b) (6)	03 Feb 2021 18:10:20

US3352349

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

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User entered 'mRNA-1273'	System	03 Feb 2021 18:10:20
DataPoint set to visible.	System	03 Feb 2021 18:03:42

US3352349

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

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:59:29
User entered '03 Feb 2021'	(b) (4), (b) (6)	03 Feb 2021 18:10:20

US3352349

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

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:59:29
User entered '11:08'	(b) (4), (b) (6)	03 Feb 2021 18:10:20

US3352349

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

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User entered '03 Feb 2021 11:08'	System	03 Feb 2021 18:10:20

US3352349

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

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:59:29
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	03 Feb 2021 18:10:20

US3352349

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

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:59:29
User entered 'ONCE'	System	03 Feb 2021 18:10:20

US3352349

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

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User entered 'INTRAMUSCULAR'	System	03 Feb 2021 18:10:20

US3352349

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:15:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:00:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Feb 2021 18:14:39

US3352349

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:15:59

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:00:16
User entered '03 Feb 2021'	(b) (4), (b) (6)	03 Feb 2021 18:14:39

US3352349

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:15:59

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:09:10
Query 'Source states 10:42. Please review and update accordingly. ' canceled (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 20:09:08
User entered '10:42' reason for change: Data Entry Error	Matthew Muniz (b) (4)	20 Apr 2021 19:28:55
User opened query 'Source states 10:42. Please review and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 15:00:14
User entered '10:40'	(b) (4), (b) (6)	03 Feb 2021 18:14:39

US3352349

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User entered '03 Feb 2021 10:42'	System	20 Apr 2021 19:28:55
User entered '03 Feb 2021 10:40'	System	03 Feb 2021 18:14:39

US3352349

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:15:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:00:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Feb 2021 18:15:08

US3352349

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:15:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:00:25
User entered '03 Feb 2021'	(b) (4), (b) (6)	03 Feb 2021 18:15:08

US3352349

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:15:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:00:25
User entered '10:39'	(b) (4), (b) (6)	03 Feb 2021 18:15:08

US3352349

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User entered '03 Feb 2021 10:39'	System	03 Feb 2021 18:15:08

US3352349

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

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:00:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Feb 2021 18:15:15

US3352349

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

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:35
User entered '1'	System	03 Feb 2021 18:15:15

US3352349

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:47:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:51:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Feb 2021 14:16:53

US3352349

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:47:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:51:30
User entered '12 Feb 2021'	(b) (4), (b) (6)	12 Feb 2021 14:16:53

US3352349

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:47:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:51:30
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	12 Feb 2021 14:16:53

US3352349

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:47:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:51:30
User entered empty.	(b) (4), (b) (6)	12 Feb 2021 14:16:53

US3352349

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:47:20
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:51:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Feb 2021 14:16:57

US3352349

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:47:20
User entered 'I'	System	12 Feb 2021 14:16:57

US3352349

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:47:20
User entered '1'	System	12 Feb 2021 14:16:57
DataPoint set to visible.	System	12 Feb 2021 14:16:57

US3352349

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:15:59

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
DataPoint set to visible.	System	12 Feb 2021 14:16:57

US3352349

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	26 Apr 2021 21:31:59

US3352349

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Apr 2021 21:31:59

US3352349

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	26 Apr 2021 21:32:08

US3352349

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:59

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Apr 2021 21:32:08

US3352349

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:15:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	26 Apr 2021 21:32:19

US3352349

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
User entered '26 Apr 2021'	Matthew Muniz (b) (4)	26 Apr 2021 21:32:19

US3352349

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
User entered 'Clinic (Clinic)'	Matthew Muniz (b) (4)	26 Apr 2021 21:32:19

US3352349

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:15:59

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	26 Apr 2021 21:32:19

US3352349

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	26 Apr 2021 21:33:43

US3352349

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
User entered '26 Apr 2021'	Matthew Muniz (b) (4)	26 Apr 2021 21:33:43

US3352349

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
User entered '10:13'	Matthew Muniz (b) (4)	26 Apr 2021 21:33:43

US3352349

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
User entered '26 Apr 2021 10:13'	System	26 Apr 2021 21:33:43

US3352349

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
User entered '37.1' C	Matthew Muniz (b) (4)	26 Apr 2021 21:33:43

US3352349

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
User entered 'Oral (Oral)'	Matthew Muniz (b) (4)	26 Apr 2021 21:33:43

US3352349

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
User entered empty.	Matthew Muniz (b) (4)	26 Apr 2021 21:33:43

US3352349

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
User entered '94'	Matthew Muniz (b) (4)	26 Apr 2021 21:33:43

US3352349

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	26 Apr 2021 21:33:43

US3352349

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
User entered '13'	Matthew Muniz (b) (4)	26 Apr 2021 21:33:43

US3352349

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	26 Apr 2021 21:33:43

US3352349

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
User entered '132'	Matthew Muniz (b) (4)	26 Apr 2021 21:33:43

US3352349

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	26 Apr 2021 21:33:43

US3352349

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
User entered '88'	Matthew Muniz (b) (4)	26 Apr 2021 21:33:43

US3352349

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	26 Apr 2021 21:33:43

US3352349

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:15:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
User entered 'No (N)'	Matthew Muniz (b) (4)	26 Apr 2021 21:33:46

US3352349

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:15:59

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
User entered empty.	Matthew Muniz (b) (4)	26 Apr 2021 21:33:46

US3352349

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:15:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	26 Apr 2021 21:34:01

US3352349

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:15:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
User entered '26 Apr 2021'	Matthew Muniz (b) (4)	26 Apr 2021 21:34:01

US3352349

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
User entered '10:43'	Matthew Muniz (b) (4)	26 Apr 2021 21:34:01

US3352349

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:15:59

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

Audit	User	Time (GMT)
User entered '26 Apr 2021 10:43'	System	26 Apr 2021 21:34:01

US3352349

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:15:59

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:16:18
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:39:36
DataPoint Un-verified.	(b) (4), (b) (6)	01 Apr 2021 19:28:17
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	01 Apr 2021 19:28:17
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 14:55:15
User entered 'No (N)'	(b) (4), (b) (6)	19 Jan 2021 14:44:03

US3352349

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 15:47:51
User entered 'USA-US066-2021-mRNA-1273-P301000010'	System	02 Apr 2021 15:47:44
User entered 'New'	(b) (4), (b) (6)	02 Apr 2021 15:47:44

US3352349

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:16
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Hepatobiliary and spleen infections, PT: Hepatic infection, LLT: Hepatic infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Apr 2021 13:23:59
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Apr 2021 13:23:59
Data point term sent to Coder	System	01 Apr 2021 19:30:20
User entered 'Unspecified Liver Infection'	(b) (4), (b) (6)	01 Apr 2021 19:29:38

US3352349

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:52:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Apr 2021 19:29:38

US3352349

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:13
User entered 'No (N)'	(b) (4), (b) (6)	01 Apr 2021 19:29:38

US3352349

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:40:12
User entered 'No (N)'	(b) (4), (b) (6)	01 Apr 2021 19:29:38

US3352349

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:32
User entered '26 Feb 2021'	(b) (4), (b) (6)	01 Apr 2021 19:29:38

US3352349

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:34
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:29:38

US3352349

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 19:29:38

US3352349

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 14:00:03
DataPoint Un-verified.	Rosaidaliz Carreira (b) (4)	28 Apr 2021 19:10:00
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Rosaidaliz Carreira (b) (4)	28 Apr 2021 19:10:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:41:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Apr 2021 19:29:38

US3352349

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 14:00:03
User closed query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 12:55:42
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' answered with 'Data updated.' (Site from Safety).	Rosaidaliz Carreira (b) (4) (b) (4)	28 Apr 2021 19:10:29
DataPoint Un-verified.	Rosaidaliz Carreira (b) (4) (b) (4)	28 Apr 2021 19:10:00
User entered '24 Apr 2021' reason for change: New Information	Rosaidaliz Carreira (b) (4) (b) (4)	28 Apr 2021 19:10:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:49
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 12:49:51
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:29:38

US3352349

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:51
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:29:38

US3352349

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 19:29:38

US3352349

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:41:55
User entered 'Grade 4 (Grade 4)'	(b) (4), (b) (6)	01 Apr 2021 19:29:38

US3352349

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:03
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	01 Apr 2021 19:30:01
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	01 Apr 2021 19:29:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Apr 2021 19:29:38

US3352349

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:11
User entered '0'	(b) (4), (b) (6)	01 Apr 2021 19:29:38

US3352349

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:13
User entered '0'	(b) (4), (b) (6)	01 Apr 2021 19:29:38

US3352349

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:15
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		01 Apr 2021 19:30:01
Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		01 Apr 2021 19:30:01
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 19:30:01
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	01 Apr 2021 19:29:38
User entered '0'	(b) (4), (b) (6)	01 Apr 2021 19:29:38

US3352349

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:22
User entered '26 Feb 2021'	(b) (4), (b) (6)	01 Apr 2021 19:29:38

US3352349

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:24
User entered '26 Mar 2021'	(b) (4), (b) (6)	01 Apr 2021 19:29:38

US3352349

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:40:46
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	01 Apr 2021 19:29:38
User entered 'Unknown (UNK)'	(b) (4), (b) (6)	01 Apr 2021 19:29:38

US3352349

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:40:46
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:29:38

US3352349

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:47
User entered '0'	(b) (4), (b) (6)	01 Apr 2021 19:29:38

US3352349

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:48
User entered '0'	(b) (4), (b) (6)	01 Apr 2021 19:29:38

US3352349

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:50
User entered '0'	(b) (4), (b) (6)	01 Apr 2021 19:29:38

US3352349

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:41
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	01 Apr 2021 19:29:38

US3352349

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:42
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	01 Apr 2021 19:29:38

US3352349

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 14:00:03
User closed query 'PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on 03 Feb 2021, then event occurred).' (Site from Safety).	(b) (4), (b) (6)	28 Apr 2021 16:45:38
Query 'PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on 03 Feb 2021, then event occurred).' answered with 'Subject refused second dose of mRNA-1273.' (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 20:11:29
DataPoint Un-verified.	(b) (4), (b) (6)	27 Apr 2021 20:10:56
User entered 'None (NONE)' reason for change:	(b) (4), (b) (6)	27 Apr 2021 20:10:56
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:44
User opened query 'PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on 03 Feb 2021, then event occurred).' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 12:48:57
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	01 Apr 2021 19:29:38

US3352349

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:55
User entered '0'	(b) (4), (b) (6)	01 Apr 2021 19:29:38

US3352349

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:43:01
User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 12:49:19
User entered 'I'	(b) (4), (b) (6)	01 Apr 2021 19:29:38

US3352349

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:40:46
User entered '0'	(b) (4), (b) (6)	01 Apr 2021 19:29:38

US3352349

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 14:00:03
DataPoint Un-verified.	Rosaidaliz Carreira (b) (4)	28 Apr 2021 19:10:00
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
Data Entry Error	Rosaidaliz Carreira (b) (4)	28 Apr 2021 19:10:00
DataPoint Verified.	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:40:46
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 12:50:03
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	01 Apr 2021 19:29:38

US3352349

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:40:46
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:29:38

US3352349

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:40:46
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 12:50:23
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 12:50:13
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 12:49:35
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 12:48:46
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	01 Apr 2021 19:32:07
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	01 Apr 2021 19:32:07

US3352349

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject was contacted in regards in scheduling his open label day 29 visit. Subject stated he will not be coming in due to a prolongation of hospitalization. Subject stated he was diagnosed with a liver infection. He also said that currently he was receiving antibiotics through an IV but was unaware of the antibiotics name. Medical records will be requested.' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 19:32:07
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	01 Apr 2021 19:29:38
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:29:38

US3352349

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Apr 2021 19:29:38

US3352349

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:59

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Apr 2021 19:29:38

US3352349

Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	01 Apr 2021 19:29:38

US3352349

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:15:59

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 14:54:58
User entered 'No (N)'	Matthew Muniz (b) (4)	19 Jan 2021 14:43:50

US3352349

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:15:59

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 14:55:09
User entered 'No (N)'	Matthew Muniz (b) (4)	19 Jan 2021 14:44:13

US3352349

Folder: SAE USA-US066-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:51:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 15:48:05
User entered 'USA-US066-2021-MRNA-1273-P301000010'	System	02 Apr 2021 15:47:44

US3352349

Folder: SAE USA-US066-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:51:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 15:48:08
User entered 'Yes (Y)'	System	02 Apr 2021 15:47:44

US3352349

Folder: SAE USA-US066-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:51:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 15:48:08
User entered 'No (N)'	System	02 Apr 2021 15:47:44

US3352349

Folder: SAE USA-US066-2021-MRNA-1273-P301000010

Form: Safety Report Form

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:51:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 15:48:08
User entered 'No (N)'	System	02 Apr 2021 15:47:44

US3352349

Folder: SAE USA-US066-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:51:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 15:48:08
User entered 'Yes (Y)'	System	02 Apr 2021 15:47:44

US3352349

Folder: SAE USA-US066-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:51:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 15:48:08
User entered 'No (N)'	System	02 Apr 2021 15:47:44

US3352349

Folder: SAE USA-US066-2021-MRNA-1273-P301000010

Form: Safety Report Form

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:51:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 15:48:08
User entered 'No (N)'	System	02 Apr 2021 15:47:44

US3352349

Folder: SAE USA-US066-2021-MRNA-1273-P301000010

Form: Safety Report Form

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:51:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 15:48:08
User entered 'No (N)'	System	02 Apr 2021 15:47:44

US3352349

Folder: SAE USA-US066-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 15:19:34
DataPoint Un-verified.	(b) (4), (b) (6)	30 Apr 2021 11:56:37
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 11:56:04
Un-reviewed for Safety.	System	29 Apr 2021 12:56:22
DataPoint Un-verified.	System	29 Apr 2021 12:56:22
Signature has been broken.	System	29 Apr 2021 12:56:22
User entered 'Surisaday'	System	29 Apr 2021 12:56:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:51:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 15:48:08
User entered 'Howard'	System	02 Apr 2021 15:47:44

US3352349

Folder: SAE USA-US066-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 15:19:34
DataPoint Un-verified.	(b) (4), (b) (6)	30 Apr 2021 11:56:38
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 11:56:04
Un-reviewed for Safety.	System	29 Apr 2021 12:56:22
DataPoint Un-verified.	System	29 Apr 2021 12:56:22
Signature has been broken.	System	29 Apr 2021 12:56:22
User entered 'Mederos'	System	29 Apr 2021 12:56:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:51:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 15:48:08
User entered 'schwartz'	System	02 Apr 2021 15:47:44

US3352349

Folder: SAE USA-US066-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 15:19:34
DataPoint Un-verified.	(b) (4), (b) (6)	30 Apr 2021 11:56:39
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 11:56:04
Un-reviewed for Safety.	System	29 Apr 2021 12:56:22
DataPoint Un-verified.	System	29 Apr 2021 12:56:22
Signature has been broken.	System	29 Apr 2021 12:56:22
User entered '9299 SW 152 ST'	System	29 Apr 2021 12:56:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:51:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 15:48:08
User entered '7265 SHeridan Street SUite 210'	System	02 Apr 2021 15:47:44

US3352349

Folder: SAE USA-US066-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 15:19:34
DataPoint Un-verified.	(b) (4), (b) (6)	30 Apr 2021 11:56:41
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 11:56:04
Un-reviewed for Safety.	System	29 Apr 2021 12:56:22
DataPoint Un-verified.	System	29 Apr 2021 12:56:22
Signature has been broken.	System	29 Apr 2021 12:56:22
User entered 'Miami'	System	29 Apr 2021 12:56:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:51:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 15:48:08
User entered 'Pembroke Pines'	System	02 Apr 2021 15:47:44

US3352349

Folder: SAE USA-US066-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:51:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 15:48:08
User entered 'FL'	System	02 Apr 2021 15:47:44

US3352349

Folder: SAE USA-US066-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 11:56:04
Un-reviewed for Safety.	System	29 Apr 2021 12:56:22
DataPoint Un-verified.	System	29 Apr 2021 12:56:22
Signature has been broken.	System	29 Apr 2021 12:56:22
User entered '33031'	System	29 Apr 2021 12:56:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:51:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 15:48:08
User entered '33024'	System	02 Apr 2021 15:47:44

US3352349

Folder: SAE USA-US066-2021-MRNA-1273-P301000010

Form: Safety Report Form

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[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:51:52
User entered 'US'	System	02 Apr 2021 15:48:15

US3352349

Folder: SAE USA-US066-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	29 Apr 2021 12:56:22
User entered '1'	System	02 Apr 2021 15:48:15

US3352349

Folder: SAE USA-US066-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:51:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 15:48:05
User entered 'USA-US066-2021-MRNA-1273-P301000010'	System	02 Apr 2021 15:47:44

US3352349

Folder: SAE USA-US066-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:51:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 15:48:08
User entered 'Yes (Y)'	System	02 Apr 2021 15:47:44

US3352349

Folder: SAE USA-US066-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:51:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 15:48:08
User entered 'No (N)'	System	02 Apr 2021 15:47:44

US3352349

Folder: SAE USA-US066-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:51:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 15:48:08
User entered 'No (N)'	System	02 Apr 2021 15:47:44

US3352349

Folder: SAE USA-US066-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:51:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 15:48:08
User entered 'Yes (Y)'	System	02 Apr 2021 15:47:44

US3352349

Folder: SAE USA-US066-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:51:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 15:48:08
User entered 'No (N)'	System	02 Apr 2021 15:47:44

US3352349

Folder: SAE USA-US066-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:51:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 15:48:08
User entered 'No (N)'	System	02 Apr 2021 15:47:44

US3352349

Folder: SAE USA-US066-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:51:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 15:48:08
User entered 'No (N)'	System	02 Apr 2021 15:47:44

US3352349

Folder: SAE USA-US066-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 15:19:34
DataPoint Un-verified.	(b) (4), (b) (6)	30 Apr 2021 11:56:37
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 11:56:04
Un-reviewed for Safety.	System	29 Apr 2021 12:56:22
DataPoint Un-verified.	System	29 Apr 2021 12:56:22
Signature has been broken.	System	29 Apr 2021 12:56:22
User entered 'Surisaday'	System	29 Apr 2021 12:56:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:51:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 15:48:08
User entered 'Howard'	System	02 Apr 2021 15:47:44

US3352349

Folder: SAE USA-US066-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 15:19:34
DataPoint Un-verified.	(b) (4), (b) (6)	30 Apr 2021 11:56:38
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 11:56:04
Un-reviewed for Safety.	System	29 Apr 2021 12:56:22
DataPoint Un-verified.	System	29 Apr 2021 12:56:22
Signature has been broken.	System	29 Apr 2021 12:56:22
User entered 'Mederos'	System	29 Apr 2021 12:56:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:51:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 15:48:08
User entered 'schwartz'	System	02 Apr 2021 15:47:44

US3352349

Folder: SAE USA-US066-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 15:19:34
DataPoint Un-verified.	(b) (4), (b) (6)	30 Apr 2021 11:56:39
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 11:56:04
Un-reviewed for Safety.	System	29 Apr 2021 12:56:22
DataPoint Un-verified.	System	29 Apr 2021 12:56:22
Signature has been broken.	System	29 Apr 2021 12:56:22
User entered '9299 SW 152 ST'	System	29 Apr 2021 12:56:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:51:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 15:48:08
User entered '7265 SHeridan Street SUite 210'	System	02 Apr 2021 15:47:44

US3352349

Folder: SAE USA-US066-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 15:19:34
DataPoint Un-verified.	(b) (4), (b) (6)	30 Apr 2021 11:56:41
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 11:56:04
Un-reviewed for Safety.	System	29 Apr 2021 12:56:22
DataPoint Un-verified.	System	29 Apr 2021 12:56:22
Signature has been broken.	System	29 Apr 2021 12:56:22
User entered 'Miami'	System	29 Apr 2021 12:56:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:51:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 15:48:08
User entered 'Pembroke Pines'	System	02 Apr 2021 15:47:44

US3352349

Folder: SAE USA-US066-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:51:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 15:48:08
User entered 'FL'	System	02 Apr 2021 15:47:44

US3352349

Folder: SAE USA-US066-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 11:56:04
Un-reviewed for Safety.	System	29 Apr 2021 12:56:22
DataPoint Un-verified.	System	29 Apr 2021 12:56:22
Signature has been broken.	System	29 Apr 2021 12:56:22
User entered '33031'	System	29 Apr 2021 12:56:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:51:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 15:48:08
User entered '33024'	System	02 Apr 2021 15:47:44

US3352349

Folder: SAE USA-US066-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:51:52
User entered 'US'	System	02 Apr 2021 15:48:15

US3352349

Folder: SAE USA-US066-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	29 Apr 2021 12:56:22
User entered '1'	System	02 Apr 2021 15:48:15

US3352349

Folder: SAE USA-US066-2021-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:15:59

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:51:52
User entered '02/Apr/2021 11:48'	System	02 Apr 2021 15:48:15

US3352349

Folder: SAE USA-US066-2021-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:15:59

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:51:52
User entered 'I'	(b) (4), (b) (6)	02 Apr 2021 15:48:15

US3352349

Folder: SAE USA-US066-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:51:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 15:48:05
User entered 'USA-US066-2021-MRNA-1273-P301000010'	System	02 Apr 2021 15:47:44

US3352349

Folder: SAE USA-US066-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:51:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 15:48:08
User entered 'Yes (Y)'	System	02 Apr 2021 15:47:44

US3352349

Folder: SAE USA-US066-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:51:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 15:48:08
User entered 'No (N)'	System	02 Apr 2021 15:47:44

US3352349

Folder: SAE USA-US066-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:51:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 15:48:08
User entered 'No (N)'	System	02 Apr 2021 15:47:44

US3352349

Folder: SAE USA-US066-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:51:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 15:48:08
User entered 'Yes (Y)'	System	02 Apr 2021 15:47:44

US3352349

Folder: SAE USA-US066-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:51:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 15:48:08
User entered 'No (N)'	System	02 Apr 2021 15:47:44

US3352349

Folder: SAE USA-US066-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:51:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 15:48:08
User entered 'No (N)'	System	02 Apr 2021 15:47:44

US3352349

Folder: SAE USA-US066-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:51:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 15:48:08
User entered 'No (N)'	System	02 Apr 2021 15:47:44

US3352349

Folder: SAE USA-US066-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 15:19:34
DataPoint Un-verified.	(b) (4), (b) (6)	30 Apr 2021 11:56:37
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 11:56:04
Un-reviewed for Safety.	System	29 Apr 2021 12:56:22
DataPoint Un-verified.	System	29 Apr 2021 12:56:22
Signature has been broken.	System	29 Apr 2021 12:56:22
User entered 'Surisaday'	System	29 Apr 2021 12:56:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:51:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 15:48:08
User entered 'Howard'	System	02 Apr 2021 15:47:44

US3352349

Folder: SAE USA-US066-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 15:19:34
DataPoint Un-verified.	(b) (4), (b) (6)	30 Apr 2021 11:56:38
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 11:56:04
Un-reviewed for Safety.	System	29 Apr 2021 12:56:22
DataPoint Un-verified.	System	29 Apr 2021 12:56:22
Signature has been broken.	System	29 Apr 2021 12:56:22
User entered 'Mederos'	System	29 Apr 2021 12:56:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:51:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 15:48:08
User entered 'schwartz'	System	02 Apr 2021 15:47:44

US3352349

Folder: SAE USA-US066-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 15:19:34
DataPoint Un-verified.	(b) (4), (b) (6)	30 Apr 2021 11:56:39
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 11:56:04
Un-reviewed for Safety.	System	29 Apr 2021 12:56:22
DataPoint Un-verified.	System	29 Apr 2021 12:56:22
Signature has been broken.	System	29 Apr 2021 12:56:22
User entered '9299 SW 152 ST'	System	29 Apr 2021 12:56:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:51:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 15:48:08
User entered '7265 SHeridan Street SUite 210'	System	02 Apr 2021 15:47:44

US3352349

Folder: SAE USA-US066-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 15:19:34
DataPoint Un-verified.	(b) (4), (b) (6)	30 Apr 2021 11:56:41
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 11:56:04
Un-reviewed for Safety.	System	29 Apr 2021 12:56:22
DataPoint Un-verified.	System	29 Apr 2021 12:56:22
Signature has been broken.	System	29 Apr 2021 12:56:22
User entered 'Miami'	System	29 Apr 2021 12:56:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:51:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 15:48:08
User entered 'Pembroke Pines'	System	02 Apr 2021 15:47:44

US3352349

Folder: SAE USA-US066-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:51:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 15:48:08
User entered 'FL'	System	02 Apr 2021 15:47:44

US3352349

Folder: SAE USA-US066-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 11:56:04
Un-reviewed for Safety.	System	29 Apr 2021 12:56:22
DataPoint Un-verified.	System	29 Apr 2021 12:56:22
Signature has been broken.	System	29 Apr 2021 12:56:22
User entered '33031'	System	29 Apr 2021 12:56:22
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:51:52
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 15:48:08
User entered '33024'	System	02 Apr 2021 15:47:44

US3352349

Folder: SAE USA-US066-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 15:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:51:52
User entered 'US'	System	02 Apr 2021 15:48:15

US3352349

Folder: SAE USA-US066-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 17:15:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	29 Apr 2021 12:56:22
User entered '1'	System	02 Apr 2021 15:48:15

US3352349

Folder: SAE USA-US066-2021-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:15:59

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 11:56:04
User entered '29/Apr/2021 05:56'	System	29 Apr 2021 12:56:22

US3352349

Folder: SAE USA-US066-2021-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:15:59

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 11:56:04
User entered 'I'	(b) (4), (b) (6)	29 Apr 2021 12:56:22