

US3392149 (Prod: Benchmark Research - Metairie - PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:27:05

All time stamps listed in this document are displayed in GMT

US3392149

Form: Participant Creation

Data signed: (b) (4) 28 Apr 2021 22:18:01

Generated On: 09 Jun 2021 17:27:05

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[Participant ID](#)

US3392149

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

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US3392149

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 03:14:28

Generated On: 09 Jun 2021 17:27:05

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 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) 20 Feb 2021 03:14:24

Generated On: 09 Jun 2021 17:27:05

Date of Birth (MMM yyyy)	(b) (6) 1990
Age	30
Age Units	YEARS
Age (Derived)	30
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	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) 20 Feb 2021 03:14:24

Generated On: 09 Jun 2021 17:27:05

Date of Informed Consent (*dd MMM yyyy*) 2 SEP 2020

Month and Year of Informed Consent (derived) SEP 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1	<input type="radio"/>
Amendment 2	<input type="radio"/>
Amendment 3	<input checked="" type="radio"/>
Amendment 4	<input type="radio"/>
Amendment 5	<input type="radio"/>

Was participant enrolled in the study?

Yes	<input checked="" type="radio"/>
No	<input type="radio"/>

If No, indicate reason for screen fail

Withdrew Consent	<input type="radio"/>
Inclusion/Exclusion	<input type="radio"/>
Cohort Full	<input type="radio"/>
Other	<input type="radio"/>

If reason for screen fail is Other, specify \_\_\_\_\_

Was this participant screened previously?

Yes	<input type="radio"/>
No	<input checked="" type="radio"/>

If Yes, previous participant number \_\_\_\_\_

Enrollment Trigger 1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 20 Feb 2021 03:14:24

Generated On: 09 Jun 2021 17:27:05

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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) 20 Feb 2021 03:14:28

Generated On: 09 Jun 2021 17:27:05

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Were any significant conditions reported?

Yes ☐

No ☒

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 20 Feb 2021 03:14:28

Generated On: 09 Jun 2021 17:27:05

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	2 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	13:39 (24 HR)
Vital Signs Date and Time (derived)	2 SEP 2020 13:39
Height ( <i>xxx.x</i> )	73 in
Weight ( <i>xxx.x</i> )	210 lb
BMI ( <i>xxx.x</i> )	27.76409 kg/m <sup>2</sup>
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) 20 Feb 2021 03:14:28

Generated On: 09 Jun 2021 17:27:05

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 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) 20 Feb 2021 03:14:28

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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 ☒

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**Specify**

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**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) 20 Feb 2021 03:14:28

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 02:53:26

Generated On: 09 Jun 2021 17:27:05

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 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) 20 Feb 2021 02:53:26

Generated On: 09 Jun 2021 17:27:05

What was the date of randomization? (dd MMM yyyy) 02 SEP 2020

What was the participant's randomization number? 145592

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) 20 Feb 2021 02:53:26

Generated On: 09 Jun 2021 17:27:05

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) 20 Feb 2021 02:53:26

Generated On: 09 Jun 2021 17:27:05

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)	02 SEP 2020
Time of assessment (00:00-23:59)	13:39 (24 HR)
Vital Signs Date and Time (derived)	02 SEP 2020 13:39
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Feb 2021 02:53:26

Generated On: 09 Jun 2021 17:27:05

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)	02 SEP 2020
Time of assessment (00:00-23:59)	15:12 (24 HR)
Vital Signs Date and Time (derived)	02 SEP 2020 15:12
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG



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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 02:53:25

Generated On: 09 Jun 2021 17:27:05

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 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: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 20 Feb 2021 02:53:25

Generated On: 09 Jun 2021 17:27:05

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) 2 SEP 2020

What was the treatment time? (00:00-23:59) 14:39 (24 HR)

Treatment Date and Time (derived) 2 SEP 2020 14:39

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) 20 Feb 2021 02:53:25

Generated On: 09 Jun 2021 17:27:05

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

02 SEP 2020

Collection time (00:00-23:59)

14:10 (24 HR)

Collection date and time (derived)

02 SEP 2020 14:10

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 02:53:25

Generated On: 09 Jun 2021 17:27:05

Collection date (dd MMM yyyy)			02 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:05	02 SEP 2020 14:05
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 02:53:25

Generated On: 09 Jun 2021 17:27:05

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 17:27:05

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

02 SEP 2020 15:16

PC Open Date & Time

02 SEP 2020 14:59

PC Close Date & Time

02 SEP 2020 17:29

US3392149

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:27:05

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.2 °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	02 SEP 2020 19:32
PC Open Date & Time	02 SEP 2020 18:24
PC Close Date & Time	03 SEP 2020 11:59

US3392149

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:27:05

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 13:47

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59



US3392149

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:27:05

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	99.7 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To <b>TREAT</b> pain or fever that has already occurred	True
To <b>PREVENT</b> pain or fever from occurring	False
PC Time Stamp	04 SEP 2020 17:56
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3392149

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:27:05

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	99.0 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To <b>TREAT</b> pain or fever that has already occurred	False
To <b>PREVENT</b> pain or fever from occurring	True

PC Time Stamp	05 SEP 2020 19:27
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3392149

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:27:05

**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

99.4 °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

06 SEP 2020 17:37

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:27:05

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °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

07 SEP 2020 19:41

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3392149

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:27:05

**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

98.8 °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

08 SEP 2020 19:53

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3392149

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:27:05

**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

02 SEP 2020 15:17

PC Open Date & Time

02 SEP 2020 14:59

PC Close Date & Time

02 SEP 2020 17:29

US3392149

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:27:05

**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

02 SEP 2020 19:33

PC Open Date & Time

02 SEP 2020 18:24

PC Close Date & Time

03 SEP 2020 11:59

US3392149

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:27:05

**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

03 SEP 2020 13:48

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59



US3392149

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:27:05

**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

04 SEP 2020 17:57

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3392149

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:27:05

**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

05 SEP 2020 19:28

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3392149

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:27:05

**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

06 SEP 2020 17:37

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3392149

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:27:05

**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

07 SEP 2020 19:41

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3392149

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:27:05

**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

08 SEP 2020 19:53

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3392149

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:27:05

**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 ☐

US3392149

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:27:05

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

No ☒

Yes ☐

PC Time stamp	02 SEP 2020 15:17
PC Open Date & Time	02 SEP 2020 14:59
PC Close Date & Time	02 SEP 2020 17:29

US3392149

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:27:05

**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 ☐



US3392149

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:27:05

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

No ☒

Yes ☐

PC Time stamp	02 SEP 2020 19:34
PC Open Date & Time	02 SEP 2020 18:24
PC Close Date & Time	03 SEP 2020 11:59

US3392149

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:27:05

**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 ☒

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Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:27:05

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 13:48
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3392149

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:27:05

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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Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:27:05

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 17:57
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3392149

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:27:05

**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 ☒

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Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:27:05

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 03:47
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3392149

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:27:05

**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 ☒



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Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:27:05

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 17:37
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3392149

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:27:05

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 ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:27:05

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 19:42
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3392149

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:27:05

**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 ☒

US3392149

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:27:05

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 19:54
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3392149

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 01:06:54

Generated On: 09 Jun 2021 17:27:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3392149

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 01:06:54

Generated On: 09 Jun 2021 17:27:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392149

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 02:33:32

Generated On: 09 Jun 2021 17:27:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3392149

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 02:33:32

Generated On: 09 Jun 2021 17:27:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392149

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 02:14:05

Generated On: 09 Jun 2021 17:27:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3392149

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 02:14:05

Generated On: 09 Jun 2021 17:27:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392149

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 04:42:06

Generated On: 09 Jun 2021 17:27:05

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

Visit date (dd MMM yyyy)	06 OCT 2020
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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	VISIT2
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US3392149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Feb 2021 04:42:06

Generated On: 09 Jun 2021 17:27:05

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)	06 OCT 2020
Time of assessment (00:00-23:59)	10:17 (24 HR)
Vital Signs Date and Time (derived)	06 OCT 2020 10:17
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG

US3392149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Feb 2021 04:42:06

Generated On: 09 Jun 2021 17:27:05

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

US3392149

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 04:42:06

Generated On: 09 Jun 2021 17:27:05

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

06 OCT 2020

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

US3392149

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 21 Feb 2021 04:42:06

Generated On: 09 Jun 2021 17:27:05

Was study treatment given? Yes ☐  
No ☒

If No, reason not given

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

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

What was the study treatment?

What was the treatment date? (dd MMM yyyy)

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

Treatment Date and Time (derived)

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

What was the frequency of the study treatment dosing?

What was the route of administration for the study treatment?



US3392149

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 04:42:06

Generated On: 09 Jun 2021 17:27:05

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	06 OCT 2020
Collection time (00:00-23:59)	10:25 (24 HR)
Collection date and time (derived)	06 OCT 2020 10:25

US3392149

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 21 Feb 2021 04:42:06

Generated On: 09 Jun 2021 17:27:05

Collection date (dd MMM yyyy)			06 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:23	06 OCT 2020 10:23
Nasopharyngeal Swab 2	No		

US3392149

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 04:42:06

Generated On: 09 Jun 2021 17:27:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392149

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 01:57:41

Generated On: 09 Jun 2021 17:27:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3392149

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 01:57:41

Generated On: 09 Jun 2021 17:27:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392149

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 01:41:27

Generated On: 09 Jun 2021 17:27:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3392149

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 01:41:27

Generated On: 09 Jun 2021 17:27:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392149

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 01:24:05

Generated On: 09 Jun 2021 17:27:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3392149

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 01:24:05

Generated On: 09 Jun 2021 17:27:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392149

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 05:23:33

Generated On: 09 Jun 2021 17:27:05

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 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

US3392149

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 21 Feb 2021 05:23:33

Generated On: 09 Jun 2021 17:27:05

Were vital signs assessed? Yes ☐  
No ☒

Date of assessment (dd MMM yyyy) \_\_\_\_\_

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

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3392149

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 05:23:33

Generated On: 09 Jun 2021 17:27:05

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.*

US3392149

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 05:23:33

Generated On: 09 Jun 2021 17:27:05

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

02 NOV 2020

Collection time (00:00-23:59)

10:20 (24 HR)

Collection date and time (derived)

02 NOV 2020 10:20

US3392149

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 05:23:33

Generated On: 09 Jun 2021 17:27:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

<b>TIMEPOINT</b>	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	02 NOV 2020 18:04:39
Patient Cloud Open Date & Time	02 NOV 2020 00:01
Patient Cloud Close Date & Time	06 NOV 2020 23:59

US3392149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 NOV 2020 05:41:13
Patient Cloud Open Date & Time	09 NOV 2020 00:01
Patient Cloud Close Date & Time	13 NOV 2020 23:59



US3392149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	16 NOV 2020 04:49:32
Patient Cloud Open Date & Time	16 NOV 2020 00:01
Patient Cloud Close Date & Time	20 NOV 2020 23:59

US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

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 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"/>

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

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[Patient Cloud Open Date & Time](#)

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20 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

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24 NOV 2020 23:59

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US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

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	30 NOV 2020 04:48:36
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

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	04 DEC 2020 04:54:32
Patient Cloud Open Date & Time	04 DEC 2020 00:01
Patient Cloud Close Date & Time	08 DEC 2020 23:59

US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

**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

11 DEC 2020 06:08:24

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59

US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

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	20 DEC 2020 17:41:12
Patient Cloud Open Date & Time	18 DEC 2020 00:01
Patient Cloud Close Date & Time	22 DEC 2020 23:59

US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

**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

25 DEC 2020 04:34:18

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59



US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

<b>TIMEPOINT</b>	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	03 JAN 2021 12:07:00
Patient Cloud Open Date & Time	01 JAN 2021 00:01
Patient Cloud Close Date & Time	05 JAN 2021 23:59

US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

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

US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

**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

15 JAN 2021 05:32:42

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

**TIMEPOINT**

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 JAN 2021 06:29:16

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

**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

29 JAN 2021 06:57:54

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	05 FEB 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	09 FEB 2021 23:59

US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>



**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

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[Patient Cloud Open Date & Time](#)

12 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

16 FEB 2021 23:59

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US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

**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 ☐

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	19 FEB 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	23 FEB 2021 23:59

US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 MAR 2021 09:11:15
Patient Cloud Open Date & Time	26 FEB 2021 00:01
Patient Cloud Close Date & Time	02 MAR 2021 23:59

US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 MAR 2021 12:01:03

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

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 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 MAR 2021 09:49:04
Patient Cloud Open Date & Time	12 MAR 2021 00:01
Patient Cloud Close Date & Time	16 MAR 2021 23:59

US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

**TIMEPOINT**

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 MAR 2021 06:28:49

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

**TIMEPOINT**

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 MAR 2021 05:24:17

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59



US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

**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

02 APR 2021 05:58:18

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

**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

11 APR 2021 12:12:38

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

**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

16 APR 2021 17:10:48

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	26 APR 2021 06:33:23
Patient Cloud Open Date & Time	23 APR 2021 00:01
Patient Cloud Close Date & Time	27 APR 2021 23:59

US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

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"/>

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

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[Patient Cloud Open Date & Time](#)

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30 APR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 MAY 2021 23:59

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US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

**TIMEPOINT**

DAY 250

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

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[Patient Cloud Open Date & Time](#)

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07 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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11 MAY 2021 23:59

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US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

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 <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"/>

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

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[Patient Cloud Open Date & Time](#)

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14 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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18 MAY 2021 23:59

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US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

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"/>

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

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[Patient Cloud Open Date & Time](#)

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21 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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25 MAY 2021 23:59

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US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

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[Patient Cloud Open Date & Time](#)

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28 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 JUN 2021 23:59

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US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

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 <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"/>

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

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[Patient Cloud Open Date & Time](#)

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04 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 JUN 2021 23:59

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US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 JUN 2021 23:59

US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

**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 ☐

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

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[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

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US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

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

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

**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 ☐

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

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[Patient Cloud Open Date & Time](#)

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02 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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06 JUL 2021 23:59

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US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

**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 ☐

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	09 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 JUL 2021 23:59

US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

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"/>

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 JUL 2021 23:59

US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

**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 ☐

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

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[Patient Cloud Open Date & Time](#)

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23 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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27 JUL 2021 23:59

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US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59



US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

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"/>

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

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[Patient Cloud Open Date & Time](#)

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06 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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10 AUG 2021 23:59

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US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

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

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

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[Patient Cloud Open Date & Time](#)

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13 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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17 AUG 2021 23:59

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US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

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[Patient Cloud Open Date & Time](#)

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20 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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24 AUG 2021 23:59

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US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

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[Patient Cloud Open Date & Time](#)

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27 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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31 AUG 2021 23:59

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US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

**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 ☐

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

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[Patient Cloud Open Date & Time](#)

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03 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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07 SEP 2021 23:59

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US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

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"/>

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

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[Patient Cloud Open Date & Time](#)

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10 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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14 SEP 2021 23:59

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US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

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[Patient Cloud Open Date & Time](#)

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17 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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21 SEP 2021 23:59

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US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

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[Patient Cloud Open Date & Time](#)

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24 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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28 SEP 2021 23:59

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US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

**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 ☐

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

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[Patient Cloud Open Date & Time](#)

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01 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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05 OCT 2021 23:59

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US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

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"/>

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

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[Patient Cloud Open Date & Time](#)

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08 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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12 OCT 2021 23:59

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US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

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"/>

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 OCT 2021 23:59

US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

**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 ☐

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

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[Patient Cloud Open Date & Time](#)

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22 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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26 OCT 2021 23:59

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US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

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"/>

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

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[Patient Cloud Open Date & Time](#)

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29 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 NOV 2021 23:59

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US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

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[Patient Cloud Open Date & Time](#)

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05 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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09 NOV 2021 23:59

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US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

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"/>

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 NOV 2021 23:59

US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

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"/>

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

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[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

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US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

**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 ☐

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	26 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 NOV 2021 23:59

US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

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"/>

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	03 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	07 DEC 2021 23:59

US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

**TIMEPOINT**

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 DEC 2021 23:59

US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

**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 ☐

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 DEC 2021 23:59



US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	24 DEC 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	28 DEC 2021 23:59
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US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

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

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

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[Patient Cloud Open Date & Time](#)

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31 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 JAN 2022 23:59

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US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

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[Patient Cloud Open Date & Time](#)

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07 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 JAN 2022 23:59

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US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

TIMEPOINT	DAY 502
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

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[Patient Cloud Open Date & Time](#)

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14 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 JAN 2022 23:59

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US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

**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 ☐

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

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[Patient Cloud Open Date & Time](#)

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21 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 JAN 2022 23:59

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US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

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[Patient Cloud Open Date & Time](#)

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28 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 FEB 2022 23:59

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US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

**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°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 ☐

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

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[Patient Cloud Open Date & Time](#)

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04 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 FEB 2022 23:59

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US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

**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 ☐

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

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[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

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US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

**TIMEPOINT**

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

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[Patient Cloud Open Date & Time](#)

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18 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 FEB 2022 23:59

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US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

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[Patient Cloud Open Date & Time](#)

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25 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 MAR 2022 23:59

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US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

**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 ☐

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

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[Patient Cloud Open Date & Time](#)

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04 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 MAR 2022 23:59

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US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

**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 ☐

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

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[Patient Cloud Open Date & Time](#)

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11 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 MAR 2022 23:59

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US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

**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 ☐

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

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[Patient Cloud Open Date & Time](#)

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18 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 MAR 2022 23:59

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US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

**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 ☐

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

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[Patient Cloud Open Date & Time](#)

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25 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 MAR 2022 23:59

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US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

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[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

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US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

TIMEPOINT	DAY 586
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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"/>

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

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[Patient Cloud Open Date & Time](#)

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08 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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12 APR 2022 23:59

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US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

**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 ☐

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 APR 2022 23:59

US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

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"/>

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

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[Patient Cloud Open Date & Time](#)

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22 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 APR 2022 23:59

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US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

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

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

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[Patient Cloud Open Date & Time](#)

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29 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 MAY 2022 23:59

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US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

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"/>

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

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[Patient Cloud Open Date & Time](#)

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06 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 MAY 2022 23:59

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US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

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"/>

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

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[Patient Cloud Open Date & Time](#)

13 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

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US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

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"/>

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

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[Patient Cloud Open Date & Time](#)

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20 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 MAY 2022 23:59

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US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

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"/>

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

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[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

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US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

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"/>

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

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[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

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US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

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"/>

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

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[Patient Cloud Open Date & Time](#)

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10 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 JUN 2022 23:59

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US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

**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 ☐

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

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[Patient Cloud Open Date & Time](#)

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17 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 JUN 2022 23:59

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US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

**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 ☐

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

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"/>

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	01 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 JUL 2022 23:59



US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

**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 ☐

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

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[Patient Cloud Open Date & Time](#)

08 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

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US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

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"/>

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 JUL 2022 23:59

US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

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="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"/>

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

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[Patient Cloud Open Date & Time](#)

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22 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 JUL 2022 23:59

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US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

**TIMEPOINT**

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

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[Patient Cloud Open Date & Time](#)

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29 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 AUG 2022 23:59

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US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

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[Patient Cloud Open Date & Time](#)

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05 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 AUG 2022 23:59

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US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	12 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	16 AUG 2022 23:59
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US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	19 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	23 AUG 2022 23:59
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US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	26 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	30 AUG 2022 23:59
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US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

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[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

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US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

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[Patient Cloud Open Date & Time](#)

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09 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 SEP 2022 23:59

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US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 SEP 2022 23:59

US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

**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 ☐

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

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[Patient Cloud Open Date & Time](#)

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23 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 SEP 2022 23:59

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US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	30 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	04 OCT 2022 23:59

US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

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

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	07 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	11 OCT 2022 23:59

US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

**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 ☐

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	14 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 OCT 2022 23:59

US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

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

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

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 OCT 2022 23:59



US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

**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 ☐

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2022 23:59

US3392149

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

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

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

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

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[Patient Cloud Open Date & Time](#)

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04 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 NOV 2022 23:59

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**US3392149**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary**

**Generated On: 09 Jun 2021 17:27:05**

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		02 MAR 2021 09:11:04

US3392149

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 22:57:34

Generated On: 09 Jun 2021 17:27:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3392149

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 22:57:34

Generated On: 09 Jun 2021 17:27:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392149

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 22:18:01

Generated On: 09 Jun 2021 17:27:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3392149

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:18:01

Generated On: 09 Jun 2021 17:27:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392149

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 22:18:01

Generated On: 09 Jun 2021 17:27:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3392149

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:18:01

Generated On: 09 Jun 2021 17:27:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392149

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 22:18:01

Generated On: 09 Jun 2021 17:27:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3392149

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:18:01

Generated On: 09 Jun 2021 17:27:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392149

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 22:18:01

Generated On: 09 Jun 2021 17:27:05

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

Visit date (dd MMM yyyy)	22 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3392149

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:05

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

US3392149

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 22:18:01

Generated On: 09 Jun 2021 17:27:05

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.*



US3392149

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 22:18:01

Generated On: 09 Jun 2021 17:27:05

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 MAR 2021
Collection time (00:00-23:59)	12:16 (24 HR)
Collection date and time (derived)	22 MAR 2021 12:16

US3392149

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:18:01

Generated On: 09 Jun 2021 17:27:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3392149**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:27:05**

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*

**US3392149**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:27:05**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: COVID-19 Contact

Data signed: (b) (4) 29 Apr 2021 20:06:21

Generated On: 09 Jun 2021 17:27:05

Date of Contact	12 SEP 2020
Time of Contact	12:00
Date and Time of Contact (derived)	12 SEP 2020 12:00
Type of Contact	<div>Clinic Visit - Scheduled <input checked="" type="radio"/></div> <div>Clinical Visit - Unscheduled <input type="radio"/></div> <div>Safety Call <input type="radio"/></div> <div>Convalescent Tele-visit <input type="radio"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes <input checked="" type="radio"/></div> <div>No <input type="radio"/></div>

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 29 Apr 2021 20:06:21

Generated On: 09 Jun 2021 17:27:05

Symptom Day

Day 1	<input checked="" type="radio"/>
Day 2	<input type="radio"/>
Day 3	<input type="radio"/>
Day 4	<input type="radio"/>
Day 5	<input type="radio"/>
Day 6	<input type="radio"/>
Day 7	<input type="radio"/>
Day 8	<input type="radio"/>
Day 9	<input type="radio"/>
Day 10	<input type="radio"/>
Day 11	<input type="radio"/>
Day 12	<input type="radio"/>
Day 13	<input type="radio"/>
Day 14	<input type="radio"/>
Day 15	<input type="radio"/>
Day 16	<input type="radio"/>
Day 17	<input type="radio"/>
Day 18	<input type="radio"/>
Day 19	<input type="radio"/>
Day 20	<input type="radio"/>
Day 21	<input type="radio"/>
Day 22	<input type="radio"/>
Day 23	<input type="radio"/>
Day 24	<input type="radio"/>
Day 25	<input type="radio"/>
Day 26	<input type="radio"/>
Day 27	<input type="radio"/>
Day 28	<input type="radio"/>
Day 29	<input type="radio"/>
Day 30	<input type="radio"/>
Day 31	<input type="radio"/>
Day 32	<input type="radio"/>

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 29 Apr 2021 20:06:21

Generated On: 09 Jun 2021 17:27:05

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	11 SEP 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	99.7 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 29 Apr 2021 20:06:21

Generated On: 09 Jun 2021 17:27:05

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>



US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 29 Apr 2021 20:06:21

Generated On: 09 Jun 2021 17:27:05

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 29 Apr 2021 20:06:21

Generated On: 09 Jun 2021 17:27:05

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input checked="" type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 29 Apr 2021 20:06:21

Generated On: 09 Jun 2021 17:27:05

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	12 SEP 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 29 Apr 2021 20:06:21

Generated On: 09 Jun 2021 17:27:05

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 29 Apr 2021 20:06:21

Generated On: 09 Jun 2021 17:27:05

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 29 Apr 2021 20:06:21

Generated On: 09 Jun 2021 17:27:05

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (3)

Data signed: (b) (4) 29 Apr 2021 20:06:21

Generated On: 09 Jun 2021 17:27:05

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	13 SEP 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (3)

Data signed: (b) (4) 29 Apr 2021 20:06:21

Generated On: 09 Jun 2021 17:27:05

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>



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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 29 Apr 2021 20:06:21

Generated On: 09 Jun 2021 17:27:05

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 29 Apr 2021 20:06:21

Generated On: 09 Jun 2021 17:27:05

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 29 Apr 2021 20:06:21

Generated On: 09 Jun 2021 17:27:05

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	14 SEP 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	102.5 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 29 Apr 2021 20:06:21

Generated On: 09 Jun 2021 17:27:05

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 29 Apr 2021 20:06:21

Generated On: 09 Jun 2021 17:27:05

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 29 Apr 2021 20:06:21

Generated On: 09 Jun 2021 17:27:05

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input checked="" type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 29 Apr 2021 20:06:21

Generated On: 09 Jun 2021 17:27:05

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	15 SEP 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	100.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 29 Apr 2021 20:06:21

Generated On: 09 Jun 2021 17:27:05

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>



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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 29 Apr 2021 20:06:21

Generated On: 09 Jun 2021 17:27:05

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 29 Apr 2021 20:06:21

Generated On: 09 Jun 2021 17:27:05

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input checked="" type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 29 Apr 2021 20:06:21

Generated On: 09 Jun 2021 17:27:05

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	16 SEP 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 29 Apr 2021 20:06:21

Generated On: 09 Jun 2021 17:27:05

	Not Done	<input checked="" type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 29 Apr 2021 20:06:21

Generated On: 09 Jun 2021 17:27:05

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Diarrhea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 29 Apr 2021 20:06:21

Generated On: 09 Jun 2021 17:27:05

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input checked="" type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 29 Apr 2021 20:06:21

Generated On: 09 Jun 2021 17:27:05

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	17 SEP 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 29 Apr 2021 20:06:21

Generated On: 09 Jun 2021 17:27:05

	Not Done	<input checked="" type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>



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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 29 Apr 2021 20:06:21

Generated On: 09 Jun 2021 17:27:05

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Diarrhea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 29 Apr 2021 20:06:21

Generated On: 09 Jun 2021 17:27:05

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input checked="" type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 29 Apr 2021 20:06:21

Generated On: 09 Jun 2021 17:27:05

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	18 SEP 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 29 Apr 2021 20:06:21

Generated On: 09 Jun 2021 17:27:05

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 29 Apr 2021 20:06:21

Generated On: 09 Jun 2021 17:27:05

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 29 Apr 2021 20:06:21

Generated On: 09 Jun 2021 17:27:05

Date of Visit	12 SEP 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	12 SEP 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

**US3392149**

**Folder: Covid-19 Assessment 12 Sep 2020**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 09 Jun 2021 17:27:05**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3392149

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 29 Apr 2021 20:06:22

Generated On: 09 Jun 2021 17:27:05

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	18 SEP 2020
Day 5	NA (COVID-19 Negative)	
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	



US3392149

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 22:18:01

Generated On: 09 Jun 2021 17:27:05

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 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	SICKD1

US3392149

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 22:18:01

Generated On: 09 Jun 2021 17:27:05

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 SEP 2020
Time of assessment (00:00-23:59)	10:10 (24 HR)
Vital Signs Date and Time (derived)	12 SEP 2020 10:10
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	99.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	170 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	104 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3392149

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 22:18:01

Generated On: 09 Jun 2021 17:27:05

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 SEP 2020

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

US3392149

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 28 Apr 2021 22:18:01

Generated On: 09 Jun 2021 17:27:05

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

12 SEP 2020

US3392149

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

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 22:18:01

Generated On: 09 Jun 2021 17:27:05

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	UNBLND_DECIDE

US3392149

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

Form: Unblinding

Data signed: (b) (4) 28 Apr 2021 22:18:01

Generated On: 09 Jun 2021 17:27:05

Date of updated informed consent ( <i>dd MMM yyyy</i> )	1 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> )	1 FEB 2021
Participant randomization assignment	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/>
Actual Dose 1	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input type="radio"/> Not Administered <input checked="" type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	
Continuing with mRNA-1273	1

US3392149

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 28 Apr 2021 22:18:01

Generated On: 09 Jun 2021 17:27:05

Height	
Weight	
BMI (xxx.x)	

US3392149

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Apr 2021 22:18:01

Generated On: 09 Jun 2021 17:27:05

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)	1 FEB 2021
Time of assessment (00:00-23:59)	13:46 (24 HR)
Vital Signs Date and Time (derived)	1 FEB 2021 13:46
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG



US3392149

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 22:18:01

Generated On: 09 Jun 2021 17:27:05

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)	1 FEB 2021
Time of assessment (00:00-23:59)	14:53 (24 HR)
Vital Signs Date and Time (derived)	1 FEB 2021 14:53
Temperature (xxx.x)	99.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

US3392149

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

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 22:18:01

Generated On: 09 Jun 2021 17:27:05

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.*

US3392149

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

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 22:18:01

Generated On: 09 Jun 2021 17:27:05

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) 1 FEB 2021

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

Treatment Date and Time (derived) 1 FEB 2021 14:23

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

What was the frequency of the study treatment dosing? ONCE

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

US3392149

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 22:18:01

Generated On: 09 Jun 2021 17:27:05

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	1 FEB 2021
Collection time (00:00-23:59)	13:54 (24 HR)
Collection date and time (derived)	1 FEB 2021 13:54

US3392149

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 28 Apr 2021 22:18:01

Generated On: 09 Jun 2021 17:27:05

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	1 FEB 2021
Collection time (00:00 - 23:59)	13:57
Collection Date and Time (derived)	1 FEB 2021 13:57

US3392149

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

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:18:01

Generated On: 09 Jun 2021 17:27:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 22:18:01

Generated On: 09 Jun 2021 17:27:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3392149

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:18:01

Generated On: 09 Jun 2021 17:27:05

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



**US3392149**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:27:05**

Was this visit performed? Yes ☐  
No ☐

Visit date (dd MMM yyyy) \_\_\_\_\_

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

Folder OID \_\_\_\_\_

US3392149

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:05

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

US3392149

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:27:05

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.*

**US3392149**

**Folder: OL-D29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:27:05**

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date ( <i>dd MMM yyyy</i> )	<hr/>
Collection time ( <i>00:00-23:59</i> )	<hr/>
Collection date and time (derived)	<hr/>

US3392149

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 28 Apr 2021 22:06:24

Generated On: 09 Jun 2021 17:27:05

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3392149

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 22:06:24

Generated On: 09 Jun 2021 17:27:05

AEID	USA-US119-2020-MRNA-1273-P30 1000003
Adverse event	HEPATITIS A
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)	24 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	25 SEP 2020
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 checked="" type="radio"/> Grade 4 <input 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)	24 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	25 SEP 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 22:06:24

Generated On: 09 Jun 2021 17:27:05

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	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	

US3392149

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 22:06:24

Generated On: 09 Jun 2021 17:27:05

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SUBJECT SEEN IN ER ON  
24SEP2020 NAUSEA WITHOUT  
EMESIS. TX'D WITH  
ANTI-EMETICS.  
JAUNDICE NO ED ON EXAM (   
TOTAL BILI : ~8.5 ) PER  
PATIENT. ADMITTED FOR  
OBSERVATION.  
DISCHARGE DX : HEPATITIS A.  
CHEMISTRTRY PANEL, AST (<39  
UNITS/L) 156 H @ 16:55 ON  
24/SEP/2020 AND 128H @02:45  
ON 25/SEP/2020.

---

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

---



US3392149

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 22:06:24

Generated On: 09 Jun 2021 17:27:05

AEID

Adverse event

HYPERTHYROIDISM

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

16 APR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 22:06:24

Generated On: 09 Jun 2021 17:27:05

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3392149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 29 Apr 2021 20:06:21

Generated On: 09 Jun 2021 17:27:05

---

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

Yes ☒

No ☐

---

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

---

US3392149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 29 Apr 2021 20:06:21

Generated On: 09 Jun 2021 17:27:05

Name of Medication ZOFRAN

Prophylaxis Yes ☐  
No ☒

Indication NAUSEA, SECONDARY TO  
HEPATITIS A

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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EAB) (1725)

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US3392149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 29 Apr 2021 20:06:21

Generated On: 09 Jun 2021 17:27:05

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	SUBLINGUAL	
Start date (dd MMM yyyy)	24 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	24 SEP 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3392149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 29 Apr 2021 20:06:21

Generated On: 09 Jun 2021 17:27:05

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication INJECTION SITE PAIN;  
HEADACHE

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3392149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 29 Apr 2021 20:06:21

Generated On: 09 Jun 2021 17:27:05

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	04 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		05 SEP 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3392149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 29 Apr 2021 20:06:21

Generated On: 09 Jun 2021 17:27:05

Name of Medication PROTONIX

Prophylaxis Yes ☐  
No ☒

Indication GASTROESOPHAGEAL REFLUX  
DISEASE, SECONDARY TO  
HEPATITIS A

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3392149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 29 Apr 2021 20:06:21

Generated On: 09 Jun 2021 17:27:05

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	24 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		24 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3392149

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 29 Apr 2021 20:06:21

Generated On: 09 Jun 2021 17:27:05

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Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3392149

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 29 Apr 2021 20:06:21

Generated On: 09 Jun 2021 17:27:05

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
24 SEP 2020	CHEMISTRY LABS	Adverse Event	
24 SEP 2020	HEMATOLOGY LABS	Adverse Event	
24 SEP 2020	COAGULATION	Adverse Event	
25 SEP 2020	ULTRASOUND	Adverse Event	

US3392149

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 28 Apr 2021 22:18:01

Generated On: 09 Jun 2021 17:27:05

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Date of dosing discontinuation (dd MMM yyyy)	06 OCT 2020
--	-------------

---

Primary reason for dosing discontinuation	AE (specify)	<input type="checkbox"/>
	SAE (specify)	<input checked="" type="checkbox"/>
	Death	<input type="checkbox"/>
	Lost To Follow-up	<input type="checkbox"/>
	Physician decision (specify)	<input type="checkbox"/>
	Pregnancy	<input type="checkbox"/>
	Protocol deviation (specify)	<input type="checkbox"/>
	Study Terminated By Sponsor	<input type="checkbox"/>
	Withdrawal of consent by participant (specify)	<input type="checkbox"/>
	Due to SARS-COV-2	<input type="checkbox"/>
Other	<input type="checkbox"/>	

---

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify	AE #1
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US3392149

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:27:05

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 ☐

US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 29 Apr 2021 20:06:22

Generated On: 09 Jun 2021 17:27:05

SAEID	USA-US119-2020-MRNA-1273-P301000003
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	MICHAEL
Investigator's Last Name	COTUGNO
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7

US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 29 Apr 2021 20:06:22

Generated On: 09 Jun 2021 17:27:05

SAEID	USA-US119-2020-MRNA-1273-P301000003
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	MICHAEL
Investigator's Last Name	COTUGNO
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	29/SEP/2020 10:14
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

US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Data signed: (b) (4) 29 Apr 2021 20:06:22

Generated On: 09 Jun 2021 17:27:05

SAEID	USA-US119-2020-MRNA-1273-P301000003
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	MICHAEL
Investigator's Last Name	COTUGNO
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	02/OCT/2020 13:17
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



US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Data signed: (b) (4) 29 Apr 2021 20:06:22

Generated On: 09 Jun 2021 17:27:05

SAEID	USA-US119-2020-MRNA-1273-P301000003
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	MICHAEL
Investigator's Last Name	COTUGNO
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	09/NOV/2020 10:45
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

US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Data signed: (b) (4) 29 Apr 2021 20:06:22

Generated On: 09 Jun 2021 17:27:05

SAEID	USA-US119-2020-MRNA-1273-P301000003
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	MICHAEL
Investigator's Last Name	COTUGNO
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	11/NOV/2020 13:02
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

US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Data signed: (b) (4) 29 Apr 2021 20:06:22

Generated On: 09 Jun 2021 17:27:05

SAEID	USA-US119-2020-MRNA-1273-P301000003
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	MICHAEL
Investigator's Last Name	COTUGNO
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	07/JAN/2021 17:49
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

US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form (6)

Data signed: (b) (4) 29 Apr 2021 20:06:22

Generated On: 09 Jun 2021 17:27:05

SAEID	USA-US119-2020-MRNA-1273-P301000003
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	MICHAEL
Investigator's Last Name	COTUGNO
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	10/MAR/2021 10:20
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

US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form (7)

Data signed: (b) (4) 29 Apr 2021 20:06:22

Generated On: 09 Jun 2021 17:27:05

SAEID	USA-US119-2020-MRNA-1273-P301000003
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	MICHAEL
Investigator's Last Name	COTUGNO
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	14/APR/2021 13:04
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

US3392149 (Prod: Benchmark Research - Metairie - PPDS)

**US3392149**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 17:27:05**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered 'US3392149'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 18:24:54

US3392149

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:27:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:47:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:14:28
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	02 Sep 2020 19:16:12



US3392149

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:27:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:47:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:14:28
User entered '02 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 18:24:55

**US3392149**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:47:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:14:28
User entered 'Clinic (Clinic)'	Brenda Lawson (b) (4)	02 Sep 2020 19:16:12

**US3392149**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:27:05**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:47:12
User entered 'SCRN'	System	02 Sep 2020 19:16:12

US3392149

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:27:05

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:47:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:14:24
User entered (b) (6) 1990'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 18:24:56

**US3392149**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:27:05**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:47:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:14:24
User entered '30'	Brenda Lawson (b) (4)	02 Sep 2020 19:16:37

**US3392149**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:27:05**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:47:12
User entered 'YEARS'	System	02 Sep 2020 19:16:37

**US3392149**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:27:05**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:47:12
User entered '30'	System	02 Sep 2020 19:16:58

**US3392149**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:27:05**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:47:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:14:24
User entered 'Male (M)'	Brenda Lawson (b) (4)	02 Sep 2020 19:16:37



**US3392149**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:27:05**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:47:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:14:24
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Brenda Lawson (b) (4)	02 Sep 2020 19:16:37

**US3392149**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:27:05**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:47:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:14:24
User entered 'I'	Brenda Lawson (b) (4)	02 Sep 2020 19:16:37

**US3392149**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:27:05**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:47:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:14:24
User entered '0'	Brenda Lawson (b) (4)	02 Sep 2020 19:16:37

**US3392149**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:27:05**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:47:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:14:24
User entered '0'	Brenda Lawson (b) (4)	02 Sep 2020 19:16:37

**US3392149**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:27:05**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:47:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:14:24
User entered '0'	Brenda Lawson (b) (4)	02 Sep 2020 19:16:37

**US3392149**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:27:05**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:47:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:14:24
User entered '0'	Brenda Lawson (b) (4)	02 Sep 2020 19:16:37

**US3392149**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:27:05**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:47:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:14:24
User entered '0'	Brenda Lawson (b) (4)	02 Sep 2020 19:16:37

**US3392149**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:27:05**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:47:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:14:24
User entered empty.	Brenda Lawson (b) (4)	02 Sep 2020 19:16:37



**US3392149**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:27:05**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:47:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:14:24
User entered '0'	Brenda Lawson (b) (4)	02 Sep 2020 19:16:37

**US3392149**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:27:05**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:47:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:14:24
User entered '0'	Brenda Lawson (b) (4)	02 Sep 2020 19:16:37

US3392149

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:27:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:47:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:14:24
User entered '2 Sep 2020'	Brenda Lawson (b) (4)	02 Sep 2020 19:16:58

**US3392149**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:47:12
User entered 'Sep 2020'	System	02 Sep 2020 19:16:58

**US3392149**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:47:12
User entered '2020'	System	02 Sep 2020 19:16:58

**US3392149**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:27:05**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:47:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:14:24
User entered 'Amendment 3 (3)'	Brenda Lawson (b) (4)	02 Sep 2020 19:16:58

**US3392149**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:47:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:14:24
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	02 Sep 2020 19:16:58

**US3392149**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:47:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:14:24
User entered empty.	Brenda Lawson (b) (4)	02 Sep 2020 19:16:58



**US3392149**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:27:05**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:47:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:14:24
User entered empty.	Brenda Lawson (b) (4)	02 Sep 2020 19:16:58

**US3392149**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:27:05**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:47:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:14:24
User entered 'No (N)'	Brenda Lawson (b) (4)	02 Sep 2020 19:16:58

**US3392149**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:27:05**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:47:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:14:24
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 18:24:55

US3392149

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:27:05

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:47:12
User entered 'I'	System	02 Sep 2020 19:17:04

**US3392149**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:47:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:14:24
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	02 Sep 2020 19:17:04

**US3392149**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 09 Jun 2021 17:27:05**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:47:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:14:28
User entered 'No (N)'	Brenda Lawson (b) (4)	02 Sep 2020 19:17:14

**US3392149**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:27:05**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:47:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:14:28
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	02 Sep 2020 19:18:23

US3392149

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:47:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:14:28
User entered '2 Sep 2020'	Brenda Lawson (b) (4)	02 Sep 2020 19:18:23



**US3392149**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:47:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:14:28
User entered '13:39'	Brenda Lawson (b) (4)	02 Sep 2020 19:18:23

**US3392149**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:47:12
User entered '2 Sep 2020 13:39'	System	02 Sep 2020 19:18:23

US3392149

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:47:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:14:28
User entered '73' in	Brenda Lawson (b) (4)	02 Sep 2020 19:18:23
DataPoint set to visible.	System	02 Sep 2020 19:17:04

**US3392149**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:47:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:14:28
User entered '210' lb	Brenda Lawson (b) (4)	02 Sep 2020 19:18:23
DataPoint set to visible.	System	02 Sep 2020 19:17:04

**US3392149**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:27:05**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:47:12
User entered '27.76409'	System	02 Sep 2020 19:18:23
DataPoint set to visible.	System	02 Sep 2020 19:17:04

**US3392149**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:27:05**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:47:12
User entered 'kg/m2'	System	02 Sep 2020 19:18:23
DataPoint set to visible.	System	02 Sep 2020 19:17:04

US3392149

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:47:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:14:28
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:03:34
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. ' answered with 'updated' (Site from DM).	Brandon Illickal (b) (4)	29 Sep 2020 19:28:07
User entered missing code ND - Not Done; reason for change Data Entry Error	Brandon Illickal (b) (4)	29 Sep 2020 19:28:02
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 18:42:51
User entered '98.5' F	Brenda Lawson (b) (4)	02 Sep 2020 19:18:23

US3392149

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:47:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:14:28
User entered empty; reason for change Data Entry Error	(b) (4) Brandon Illickal (b) (4)	29 Sep 2020 19:28:02
User entered 'Oral (Oral)'	(b) (4) Brenda Lawson (b) (4)	02 Sep 2020 19:18:23



**US3392149**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:27:05**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:47:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:14:28
User entered empty.	Brenda Lawson (b) (4)	02 Sep 2020 19:18:23

US3392149

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:47:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:14:28
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Brandon Illickal (b) (4)	29 Sep 2020 19:28:02
User entered '76'	Brenda Lawson (b) (4)	02 Sep 2020 19:18:23

**US3392149**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:27:05**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:47:12
User entered 'bpm'	System	02 Sep 2020 19:18:23

US3392149

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:47:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:14:28
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Brandon Illickal (b) (4)	29 Sep 2020 19:28:02
User entered '16'	Brenda Lawson (b) (4)	02 Sep 2020 19:18:23

US3392149

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:47:12
User entered 'breaths/min'	System	02 Sep 2020 19:18:23

US3392149

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:47:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:14:28
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Brandon Illickal (b) (4)	29 Sep 2020 19:28:02
User entered '120'	(b) (4) Brenda Lawson (b) (4)	02 Sep 2020 19:18:23

**US3392149**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:27:05**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:47:12
User entered 'mmHg'	System	02 Sep 2020 19:18:23

US3392149

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:47:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:14:28
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Brandon Illickal (b) (4)	29 Sep 2020 19:28:02
User entered '64'	Brenda Lawson (b) (4)	02 Sep 2020 19:18:23



**US3392149**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:27:05**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:47:12
User entered 'mmHg'	System	02 Sep 2020 19:18:23

**US3392149**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:27:05**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:47:12

US3392149

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:05

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:47:12

US3392149

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:27:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:47:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:14:28
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	02 Sep 2020 19:18:33

**US3392149**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:27:05**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:47:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:14:28
User entered '2 Sep 2020'	Brenda Lawson (b) (4)	02 Sep 2020 19:18:33

US3392149

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:27:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:47:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:14:28
User entered 'No (N)'	Brenda Lawson (b) (4)	02 Sep 2020 19:19:10

US3392149

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:27:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:47:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:14:28
User entered 'No (N)'	Brenda Lawson (b) (4)	02 Sep 2020 19:19:10

US3392149

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:27:05

**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)	26 Apr 2021 10:47:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:14:28
User entered 'No (N)'	Brenda Lawson (b) (4)	02 Sep 2020 19:19:10



US3392149

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)	26 Apr 2021 10:47:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:14:28
User entered 'No (N)'	Brenda Lawson (b) (4)	02 Sep 2020 19:19:10

US3392149

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:27:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:47:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:14:28
User entered 'No (N)'	Brenda Lawson (b) (4)	02 Sep 2020 19:19:10

US3392149

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:27:05

[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)	26 Apr 2021 10:47:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:14:28
User entered 'No (N)'	Brenda Lawson (b) (4)	02 Sep 2020 19:19:10

US3392149

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:27:05

**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)	26 Apr 2021 10:47:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:14:28
User entered 'No (N)'	Brenda Lawson (b) (4)	02 Sep 2020 19:19:10

US3392149

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:27:05

**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)	26 Apr 2021 10:47:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:14:28
User entered 'No (N)'	Brenda Lawson (b) (4)	02 Sep 2020 19:19:10

US3392149

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:27:05

[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)	26 Apr 2021 10:47:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:14:28
User entered 'No (N)'	Brenda Lawson (b) (4)	02 Sep 2020 19:19:10

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Folder: Screening

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**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)	26 Apr 2021 10:47:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:14:28
User entered 'No (N)'	Brenda Lawson (b) (4)	02 Sep 2020 19:19:10

US3392149

Folder: Screening

Form: Risk of Exposure

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**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)	26 Apr 2021 10:47:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:14:28
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	02 Sep 2020 19:19:10



**US3392149**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 09 Jun 2021 17:27:05**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:47:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:14:28
User entered 'No (N)'	Brenda Lawson (b) (4)	02 Sep 2020 19:19:10

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Folder: Screening

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:47:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:14:28
User entered empty.	Brenda Lawson (b) (4)	02 Sep 2020 19:19:10

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:47:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:14:28
User entered '0'	Brenda Lawson (b) (4)	02 Sep 2020 19:19:10

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Folder: Screening

Form: Risk of Exposure

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Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:47:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:14:28
User entered '0'	Brenda Lawson (b) (4)	02 Sep 2020 19:19:10

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Folder: Screening

Form: Risk of Exposure

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**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)	26 Apr 2021 10:47:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:14:28
User entered '0'	Brenda Lawson (b) (4)	02 Sep 2020 19:19:10

US3392149

Folder: Screening

Form: Risk of Exposure

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[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)	26 Apr 2021 10:47:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:14:28
User entered '0'	Brenda Lawson (b) (4)	02 Sep 2020 19:19:10

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Folder: Screening

Form: Risk of Exposure

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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)	26 Apr 2021 10:47:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:14:28
User entered '0'	Brenda Lawson (b) (4)	02 Sep 2020 19:19:10

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:47:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:14:28
User entered 'I'	Brenda Lawson (b) (4)	02 Sep 2020 19:19:10



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**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 09 Jun 2021 17:27:05**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:47:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:14:28
User entered '0'	Brenda Lawson (b) (4)	02 Sep 2020 19:19:10

US3392149

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:27:05

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:47:12
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:14:28
User entered empty.	Brenda Lawson (b) (4)	02 Sep 2020 19:19:10

**US3392149**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:27:05**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:53:26
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	02 Sep 2020 19:19:30

**US3392149**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:53:26
User entered '2 Sep 2020'	Brenda Lawson (b) (4)	02 Sep 2020 19:19:30

**US3392149**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:53:26
User entered 'Clinic (Clinic)'	Brenda Lawson (b) (4)	02 Sep 2020 19:19:30

**US3392149**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:27:05**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User entered 'VISIT1'	System	02 Sep 2020 19:19:30

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:27:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:53:26
User entered '02 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 18:54:56

US3392149

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:27:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:53:26
User entered '145592'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 18:54:56



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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:27:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:53:26
User closed query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:14:29
Query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' answered with 'DATA CHANGE REQUEST SUBMITTED VIA ENDPOINT TO CHANGE THE COHORT STRATIFICATION FOR US339-2149.' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 21:55:39
Amendment Manager: User opened query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	System	30 Sep 2020 22:15:10
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	30 Sep 2020 22:15:10
Comment added 'Subject is a student and often out and about.'	Brenda Lawson (b) (4) (b) (4)	02 Sep 2020 19:21:20
User opened query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	System	02 Sep 2020 19:19:41
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 18:54:56

**US3392149**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 17:27:05**

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)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:53:26
User entered 'No (N)'	Brenda Lawson (b) (4)	02 Sep 2020 19:19:41

**US3392149**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 17:27:05**

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)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:53:26
User entered 'No (N)'	Brenda Lawson (b) (4)	02 Sep 2020 19:19:41

**US3392149**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:53:26
User entered 'No (N)'	Brenda Lawson (b) (4)	02 Sep 2020 19:19:41

**US3392149**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:53:26
User entered 'No (N)'	Brenda Lawson (b) (4)	02 Sep 2020 19:19:41

**US3392149**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 17:27:05**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:53:26
User entered 'No (N)'	Brenda Lawson (b) (4)	02 Sep 2020 19:19:41

**US3392149**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:53:26
User entered 'No (N)'	(b) (4) Brandon Illickal (b) (4)	01 Oct 2020 21:24:40
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 04:57:36
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 04:57:35

US3392149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:27:05

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:53:26
User closed query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:03:36
Query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly. ' answered with 'updated' (Site from DM).	Brandon Illickal (b) (4)	29 Sep 2020 16:20:07
User entered missing code ND - Not Done; reason for change Data Entry Error	Brandon Illickal (b) (4)	29 Sep 2020 16:20:02
User opened query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 18:42:43
User entered '73' in	Brenda Lawson (b) (4) (b) (4)	02 Sep 2020 19:22:54



US3392149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:27:05

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:53:26
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Brandon Illickal (b) (4)	29 Sep 2020 16:20:02
User entered '210' lb	(b) (4) Brenda Lawson (b) (4)	02 Sep 2020 19:22:54

US3392149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:27:05

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:53:26
User closed query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:03:36
Query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly. ' answered with 'updated' (Site from DM).	Brandon Illickal (b) (4)	29 Sep 2020 16:20:07
User entered missing code ND - Not Done; reason for change Data Entry Error	Brandon Illickal (b) (4)	29 Sep 2020 16:20:02
User opened query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 18:42:43
User entered '73' in	Brenda Lawson (b) (4) (b) (4)	02 Sep 2020 19:22:54

US3392149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:27:05

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:53:26
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Brandon Illickal (b) (4)	29 Sep 2020 16:20:02
User entered '210' lb	Brenda Lawson (b) (4)	02 Sep 2020 19:22:54

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User accepted default value 'Pre-Dose (PREDOSE)'	Brenda Lawson (b) (4)	02 Sep 2020 19:22:54
	(b) (4)	

**US3392149**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:27:05**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:53:26
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	02 Sep 2020 19:22:54

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:53:26
User entered '02 Sep 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:06:14
User entered '2 Sep 2020'	Brenda Lawson (b) (4) (b) (4)	02 Sep 2020 19:22:54

**US3392149**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:53:26
User entered '13:39'	Brenda Lawson (b) (4)	02 Sep 2020 19:22:54

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User entered '02 Sep 2020 13:39'	System	04 Nov 2020 21:06:14
User entered '2 Sep 2020 13:39'	System	02 Sep 2020 19:22:54



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:53:26
User entered '98.5' F	Brenda Lawson (b) (4)	02 Sep 2020 19:22:54

US3392149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:53:26
User entered 'Oral (Oral)'	Brenda Lawson (b) (4)	02 Sep 2020 19:22:54

**US3392149**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:27:05**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:53:26
User entered empty.	Brenda Lawson (b) (4)	02 Sep 2020 19:22:54

**US3392149**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:27:05**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:53:26
User entered '76'	Brenda Lawson (b) (4)	02 Sep 2020 19:22:54

**US3392149**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:27:05**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User entered 'bpm'	System	02 Sep 2020 19:22:54

US3392149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:53:26
User entered '16'	Brenda Lawson (b) (4)	02 Sep 2020 19:22:54

US3392149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User entered 'breaths/min'	System	02 Sep 2020 19:22:54

US3392149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:53:26
User entered '120'	Brenda Lawson (b) (4)	02 Sep 2020 19:22:54



**US3392149**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:27:05**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User entered 'mmHg'	System	02 Sep 2020 19:22:54

US3392149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:53:26
User entered '64'	Brenda Lawson (b) (4)	02 Sep 2020 19:22:54

**US3392149**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:27:05**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User entered 'mmHg'	System	02 Sep 2020 19:22:54

US3392149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:27:05

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:53:26
User closed query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:03:36
Query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly. ' answered with 'updated' (Site from DM).	Brandon Illickal (b) (4)	29 Sep 2020 16:20:07
User entered missing code ND - Not Done; reason for change Data Entry Error	Brandon Illickal (b) (4)	29 Sep 2020 16:20:02
User opened query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 18:42:43
User entered '73' in	Brenda Lawson (b) (4) (b) (4)	02 Sep 2020 19:22:54

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:27:05

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:53:26
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Brandon Illickal (b) (4)	29 Sep 2020 16:20:02
User entered '210' lb	(b) (4) Brenda Lawson (b) (4)	02 Sep 2020 19:22:54

US3392149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User accepted default value 'Post-Dose (POSTDOSE)'	Brenda Lawson (b) (4) (b) (4)	02 Sep 2020 19:22:54

US3392149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:53:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Nov 2020 21:06:14
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Nov 2020 21:06:14
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 19:22:54
User entered empty.	Brenda Lawson (b) (4)	02 Sep 2020 19:22:54
	(b) (4)	

US3392149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:53:26
User entered '02 Sep 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:06:14
User entered empty.	Brenda Lawson (b) (4) (b) (4)	02 Sep 2020 19:22:54



**US3392149**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:53:26
User entered '15:12' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:06:14
User entered empty.	Brenda Lawson (b) (4) (b) (4)	02 Sep 2020 19:22:54

**US3392149**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User entered '02 Sep 2020 15:12'	System	04 Nov 2020 21:06:14
User entered empty.	System	02 Sep 2020 19:22:54

US3392149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:53:26
User entered '98.4' F reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:06:14
User entered empty.	Brenda Lawson (b) (4) (b) (4)	02 Sep 2020 19:22:54

US3392149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:53:26
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:06:14
User entered empty.	Brenda Lawson (b) (4) (b) (4)	02 Sep 2020 19:22:54

**US3392149**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:27:05**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:53:26
User entered empty.	Brenda Lawson (b) (4)	02 Sep 2020 19:22:54

US3392149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:53:26
User entered '68' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:06:14
User entered empty.	Brenda Lawson (b) (4) (b) (4)	02 Sep 2020 19:22:54

**US3392149**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:27:05**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User entered 'bpm'	System	04 Nov 2020 21:06:14
User entered empty.	System	02 Sep 2020 19:22:54

US3392149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:53:26
User entered '16' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:06:14
User entered empty.	Brenda Lawson (b) (4) (b) (4)	02 Sep 2020 19:22:54



US3392149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User entered 'breaths/min'	System	04 Nov 2020 21:06:14
User entered empty.	System	02 Sep 2020 19:22:54

US3392149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:53:26
User entered '115' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:06:14
User entered empty.	Brenda Lawson (b) (4) (b) (4)	02 Sep 2020 19:22:54

**US3392149**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:27:05**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User entered 'mmHg'	System	04 Nov 2020 21:06:14
User entered empty.	System	02 Sep 2020 19:22:54

US3392149

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:53:26
User entered '76' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:06:14
User entered empty.	Brenda Lawson (b) (4) (b) (4)	02 Sep 2020 19:22:54

**US3392149**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:27:05**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User entered 'mmHg'	System	04 Nov 2020 21:06:14
User entered empty.	System	02 Sep 2020 19:22:54

**US3392149**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:27:05**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:53:26
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	02 Sep 2020 19:23:06

US3392149

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:27:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:53:26
User entered '02 Sep 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:06:56
User entered '2 Sep 2020'	Brenda Lawson (b) (4) (b) (4)	02 Sep 2020 19:23:06

**US3392149**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:27:05**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:53:26
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	02 Sep 2020 19:47:41



**US3392149**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:27:05**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:53:26
User entered empty.	Brenda Lawson (b) (4)	02 Sep 2020 19:47:41

US3392149

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:27:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:53:26
User entered empty.	Brenda Lawson (b) (4)	02 Sep 2020 19:47:41

US3392149

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:27:05

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User entered 'MRNA-1273 OR PLACEBO'	System	02 Sep 2020 19:47:41

US3392149

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:27:05

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:53:26
User entered '2 Sep 2020'	Brenda Lawson (b) (4)	02 Sep 2020 19:47:41

**US3392149**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:53:26
User entered '14:39'	Brenda Lawson (b) (4)	02 Sep 2020 19:47:41

**US3392149**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User entered '2 Sep 2020 14:39'	System	02 Sep 2020 19:47:41

US3392149

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:27:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:53:26
User entered 'Left Arm (LEFT ARM)'	Brenda Lawson (b) (4)	02 Sep 2020 19:47:41

US3392149

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:27:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User entered 'ONCE'	System	02 Sep 2020 19:47:41



**US3392149**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User entered 'INTRAMUSCULAR'	System	02 Sep 2020 19:47:41

**US3392149**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:27:05**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:53:26
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	02 Sep 2020 19:23:29

US3392149

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:27:05

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:53:26
User entered '02 Sep 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:07:07
User entered '2 Sep 2020'	Brenda Lawson (b) (4) (b) (4)	02 Sep 2020 19:23:29

**US3392149**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:53:26
User entered '14:10'	Brenda Lawson (b) (4)	02 Sep 2020 19:23:29

**US3392149**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User entered '02 Sep 2020 14:10'	System	04 Nov 2020 21:07:07
User entered '2 Sep 2020 14:10'	System	02 Sep 2020 19:23:29

US3392149

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:27:05

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:53:26
User entered '02 Sep 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:07:20
User entered '2 Sep 2020'	Brenda Lawson (b) (4) (b) (4)	02 Sep 2020 19:23:55

**US3392149**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:27:05**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Brenda Lawson (b) (4)	02 Sep 2020 19:23:55

**US3392149**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:27:05**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:53:26
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	02 Sep 2020 19:23:55



**US3392149**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:53:26
User entered '14:05'	Brenda Lawson (b) (4)	02 Sep 2020 19:23:55

**US3392149**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User entered '02 Sep 2020 14:05'	System	04 Nov 2020 21:07:20
User entered '2 Sep 2020 14:05'	System	02 Sep 2020 19:23:55

**US3392149**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:27:05**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Brenda Lawson (b) (4)	02 Sep 2020 19:23:55

US3392149

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:27:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:53:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 18:26:33
User entered 'No (N)' reason for change: Per Query Resolution	System	03 Sep 2020 18:26:33
User opened query 'Data is required. Please complete.' (Site from System).	Brandon Illickal (b) (4)	03 Sep 2020 18:26:33
User entered empty.	(b) (4)	
	System	02 Sep 2020 19:23:55
	Brenda Lawson (b) (4)	02 Sep 2020 19:23:55
	(b) (4)	

**US3392149**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:53:26
User entered empty.	Brenda Lawson (b) (4)	02 Sep 2020 19:23:55

**US3392149**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User entered empty.	System	02 Sep 2020 19:23:55

US3392149

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:27:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:53:26
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	02 Sep 2020 19:24:02

**US3392149**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:27:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User entered 'I'	System	02 Sep 2020 19:24:02



US3392149

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:27:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
Data entry locked.	System	02 Sep 2020 19:47:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 19:47:41

US3392149

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:27:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-02T15:16:22', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '68259fea-526d-4df2-a91a-ce4c826dd0bc' User entered 'Yes (Y)'	System	02 Sep 2020 20:16:37
	System	02 Sep 2020 20:16:37

US3392149

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:27:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-02T15:16:26', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '68259fea-526d-4df2-a91a-ce4c826dd0bc' User entered '98.4'	System	02 Sep 2020 20:16:37
	System	02 Sep 2020 20:16:37

US3392149

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:27:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-02T15:16:30', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '68259fea-526d-4df2-a91a-ce4c826dd0bc' User entered 'No (N)'	System	02 Sep 2020 20:16:37
	System	02 Sep 2020 20:16:37

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 17:27:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-02T15:16:33', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '68259fea-526d-4df2-a91a-ce4c826dd0bc'	System	02 Sep 2020 20:16:37
User entered '02 Sep 2020 15:16'	System	02 Sep 2020 20:16:37

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 17:27:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
User entered '02 Sep 2020 14:59'	System	02 Sep 2020 19:47:41

US3392149

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:27:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
User entered '02 Sep 2020 17:29'	System	02 Sep 2020 19:47:41

US3392149

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:27:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
Data entry locked.	System	02 Sep 2020 19:47:41
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 19:47:41



**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 17:27:05**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-02T19:32:00', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '24f087b7-7d92-49fc-98be-9fd879331a2b' User entered 'Yes (Y)'	System	03 Sep 2020 00:32:18
	System	03 Sep 2020 00:32:18

US3392149

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:27:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-02T19:32:04', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '24f087b7-7d92-49fc-98be-9fd879331a2b' User entered '98.2'	System	03 Sep 2020 00:32:18
	System	03 Sep 2020 00:32:18

US3392149

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:27:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-02T19:32:08', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '24f087b7-7d92-49fc-98be-9fd879331a2b' User entered 'No (N)'	System	03 Sep 2020 00:32:18
	System	03 Sep 2020 00:32:18

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 17:27:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-02T19:32:13', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '24f087b7-7d92-49fc-98be-9fd879331a2b' User entered '02 Sep 2020 19:32'	System	03 Sep 2020 00:32:18
	System	03 Sep 2020 00:32:18

US3392149

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:27:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
User entered '02 Sep 2020 18:24'	System	02 Sep 2020 19:47:41

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 17:27:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 19:47:41

US3392149

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:27:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
Data entry locked.	System	02 Sep 2020 19:47:41
User entered 'Day 2'	System	02 Sep 2020 19:47:41

US3392149

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:27:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-03T13:46:59', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: 'fb6fc415-6a54-440a-8842-ac3022cf5132'	System	03 Sep 2020 18:47:24
User entered 'Yes (Y)'	System	03 Sep 2020 18:47:24



US3392149

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:27:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-03T13:47:03', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: 'fb6fc415-6a54-440a-8842-ac3022cf5132' User entered '98.3'	System	03 Sep 2020 18:47:24
	System	03 Sep 2020 18:47:24

US3392149

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:27:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-03T13:47:09', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: 'fb6fc415-6a54-440a-8842-ac3022cf5132'	System	03 Sep 2020 18:47:24
User entered 'No (N)'	System	03 Sep 2020 18:47:24

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 17:27:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-03T13:47:19', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: 'fb6fc415-6a54-440a-8842-ac3022cf5132'	System	03 Sep 2020 18:47:24
User entered '03 Sep 2020 13:47'	System	03 Sep 2020 18:47:24

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 17:27:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 19:47:41

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 17:27:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 19:47:41

US3392149

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:27:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
Data entry locked.	System	02 Sep 2020 19:47:41
User entered 'Day 3'	System	02 Sep 2020 19:47:41

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 17:27:05**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-04T17:56:05', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '634ba9cf-1e85-4d29-80d4-dc38664c8ebf' User entered 'Yes (Y)'	System	04 Sep 2020 22:56:37
	System	04 Sep 2020 22:56:37

US3392149

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:27:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-04T17:56:09', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '634ba9cf-1e85-4d29-80d4-dc38664c8ebf' User entered '99.7'	System	04 Sep 2020 22:56:37
	System	04 Sep 2020 22:56:37



US3392149

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:27:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-04T17:56:14', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '634ba9cf-1e85-4d29-80d4-dc38664c8ebf' User entered 'Yes (Y)'	System	04 Sep 2020 22:56:37
	System	04 Sep 2020 22:56:37

US3392149

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:27:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'TYLENOL TAKEN FOR PAIN AND FEVER AT POST VACCINE DAY 1' (Site from System).	(b) (4), (b) (6)	05 Nov 2020 06:18:40
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	04 Nov 2020 21:10:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-04T17:56:30', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '634ba9cf-1e85-4d29-80d4-dc38664c8ebf'	System	04 Sep 2020 22:56:37
User entered '1'	System	04 Sep 2020 22:56:37

US3392149

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:27:05

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-04T17:56:30', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '634ba9cf-1e85-4d29-80d4-dc38664c8ebf' User entered '0'	System	04 Sep 2020 22:56:37
	System	04 Sep 2020 22:56:37

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 17:27:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-04T17:56:35', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '634ba9cf-1e85-4d29-80d4-dc38664c8ebf' User entered '04 Sep 2020 17:56'	System	04 Sep 2020 22:56:37
	System	04 Sep 2020 22:56:37

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 17:27:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 19:47:41

US3392149

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:27:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 19:47:41

US3392149

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:27:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
Data entry locked.	System	02 Sep 2020 19:47:41
User entered 'Day 4'	System	02 Sep 2020 19:47:41

US3392149

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:27:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-05T19:27:16', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '7f0eb040-4b45-45d9-88fa-77cccd5f069d' User entered 'Yes (Y)'	System	06 Sep 2020 00:27:47
	System	06 Sep 2020 00:27:47



US3392149

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:27:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-05T19:27:28', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '7f0eb040-4b45-45d9-88fa-77cccd5f069d' User entered '99.0'	System	06 Sep 2020 00:27:47
	System	06 Sep 2020 00:27:47

US3392149

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:27:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-05T19:27:35', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '7f0eb040-4b45-45d9-88fa-77cccd5f069d'	System	06 Sep 2020 00:27:47
User entered 'Yes (Y)'	System	06 Sep 2020 00:27:47

US3392149

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:27:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-05T19:27:38', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '7f0eb040-4b45-45d9-88fa-77cccd5f069d' User entered '0'	System	06 Sep 2020 00:27:47
	System	06 Sep 2020 00:27:47

US3392149

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:27:05

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'TYLENOL TAKEN FOR PAIN AND FEVER AT POST VACCINE DAY 1' (Site from System).	(b) (4), (b) (6)	05 Nov 2020 06:18:47
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	04 Nov 2020 21:10:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-05T19:27:38', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '7f0eb040-4b45-45d9-88fa-77cccd5f069d'	System	06 Sep 2020 00:27:47
User entered '1'	System	06 Sep 2020 00:27:47

US3392149

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:27:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-05T19:27:42', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '7f0eb040-4b45-45d9-88fa-77cccd5f069d' User entered '05 Sep 2020 19:27'	System	06 Sep 2020 00:27:47
	System	06 Sep 2020 00:27:47

US3392149

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:27:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 19:47:41

US3392149

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:27:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 19:47:41

US3392149

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:27:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
Data entry locked.	System	02 Sep 2020 19:47:41
User entered 'Day 5'	System	02 Sep 2020 19:47:41



**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 17:27:05**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-06T17:36:58', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '846b483c-6ec1-4961-99b8-cf0346b08b08' User entered 'Yes (Y)'	System	06 Sep 2020 22:37:12
	System	06 Sep 2020 22:37:12

US3392149

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:27:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-06T17:37:01', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '846b483c-6ec1-4961-99b8-cf0346b08b08' User entered '99.4'	System	06 Sep 2020 22:37:12
	System	06 Sep 2020 22:37:12

US3392149

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:27:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-06T17:37:04', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '846b483c-6ec1-4961-99b8-cf0346b08b08' User entered 'No (N)'	System	06 Sep 2020 22:37:12
	System	06 Sep 2020 22:37:12

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 17:27:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-06T17:37:08', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '846b483c-6ec1-4961-99b8-cf0346b08b08' User entered '06 Sep 2020 17:37'	System	06 Sep 2020 22:37:12
	System	06 Sep 2020 22:37:12

US3392149

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:27:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 19:47:41

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 17:27:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 19:47:41

US3392149

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:27:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
Data entry locked.	System	02 Sep 2020 19:47:41
User entered 'Day 6'	System	02 Sep 2020 19:47:41

US3392149

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:27:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-07T19:41:05', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: 'c9b5b2a7-76b2-4991-b186-7b358010eb35' User entered 'Yes (Y)'	System	08 Sep 2020 00:41:37
	System	08 Sep 2020 00:41:37



US3392149

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:27:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-07T19:41:27', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: 'c9b5b2a7-76b2-4991-b186-7b358010eb35' User entered '98.7'	System	08 Sep 2020 00:41:37
	System	08 Sep 2020 00:41:37

US3392149

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:27:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-07T19:41:30', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: 'c9b5b2a7-76b2-4991-b186-7b358010eb35'	System	08 Sep 2020 00:41:37
User entered 'No (N)'	System	08 Sep 2020 00:41:37

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 17:27:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-07T19:41:32', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: 'c9b5b2a7-76b2-4991-b186-7b358010eb35' User entered '07 Sep 2020 19:41'	System	08 Sep 2020 00:41:37
	System	08 Sep 2020 00:41:37

US3392149

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:27:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 19:47:41

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 17:27:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 19:47:41

US3392149

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:27:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
Data entry locked.	System	02 Sep 2020 19:47:41
User entered 'Day 7'	System	02 Sep 2020 19:47:41

US3392149

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:27:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-08T19:52:49', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: 'a8804daf-7a86-4bfa-82c4-d52472098dd4' User entered 'Yes (Y)'	System	09 Sep 2020 00:53:06
	System	09 Sep 2020 00:53:06

US3392149

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:27:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-08T19:52:59', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: 'a8804daf-7a86-4bfa-82c4-d52472098dd4' User entered '98.8'	System	09 Sep 2020 00:53:06
	System	09 Sep 2020 00:53:06



US3392149

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:27:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-08T19:53:01', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: 'a8804daf-7a86-4bfa-82c4-d52472098dd4'	System	09 Sep 2020 00:53:06
User entered 'No (N)'	System	09 Sep 2020 00:53:06

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 17:27:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-08T19:53:04', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: 'a8804daf-7a86-4bfa-82c4-d52472098dd4' User entered '08 Sep 2020 19:53'	System	09 Sep 2020 00:53:06
	System	09 Sep 2020 00:53:06

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 17:27:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 19:47:41

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 17:27:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 19:47:41

US3392149

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:27:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
Data entry locked.	System	02 Sep 2020 19:47:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 19:47:41

US3392149

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:27:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-02T15:16:56', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '85ce881e-7365-46de-8a53-957ec1af3717'	System	02 Sep 2020 20:17:22
User entered 'Does not interfere with activity (2)'	System	02 Sep 2020 20:17:22

US3392149

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:27:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-02T15:16:59', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '85ce881e-7365-46de-8a53-957ec1af3717' User entered 'No (N)'	System	02 Sep 2020 20:17:22
	System	02 Sep 2020 20:17:22

US3392149

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:27:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-02T15:17:05', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '85ce881e-7365-46de-8a53-957ec1af3717' User entered 'No (N)'	System	02 Sep 2020 20:17:22
	System	02 Sep 2020 20:17:22



US3392149

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:27:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-02T15:17:16', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '85ce881e-7365-46de-8a53-957ec1af3717'	System	02 Sep 2020 20:17:22
User entered 'None (1)'	System	02 Sep 2020 20:17:22

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:27:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-02T15:17:19', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '85ce881e-7365-46de-8a53-957ec1af3717'	System	02 Sep 2020 20:17:22
User entered '02 Sep 2020 15:17'	System	02 Sep 2020 20:17:22

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:27:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
User entered '02 Sep 2020 14:59'	System	02 Sep 2020 19:47:41

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:27:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
User entered '02 Sep 2020 17:29'	System	02 Sep 2020 19:47:41

US3392149

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:27:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
Data entry locked.	System	02 Sep 2020 19:47:41
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 19:47:41

US3392149

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:27:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-02T19:32:38', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: 'c3f8d117-3117-487a-8b10-c690598e0743'	System	03 Sep 2020 00:33:20
User entered 'Does not interfere with activity (2)'	System	03 Sep 2020 00:33:20

US3392149

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:27:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-02T19:33:01', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: 'c3f8d117-3117-487a-8b10-c690598e0743' User entered 'No (N)'	System	03 Sep 2020 00:33:20
	System	03 Sep 2020 00:33:20

US3392149

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:27:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-02T19:33:07', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: 'c3f8d117-3117-487a-8b10-c690598e0743' User entered 'No (N)'	System	03 Sep 2020 00:33:20
	System	03 Sep 2020 00:33:20



US3392149

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:27:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-02T19:33:15', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: 'c3f8d117-3117-487a-8b10-c690598e0743' User entered 'None (1)'	System	03 Sep 2020 00:33:20
	System	03 Sep 2020 00:33:20

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:27:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-02T19:33:17', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: 'c3f8d117-3117-487a-8b10-c690598e0743' User entered '02 Sep 2020 19:33'	System	03 Sep 2020 00:33:20
	System	03 Sep 2020 00:33:20

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:27:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
User entered '02 Sep 2020 18:24'	System	02 Sep 2020 19:47:41

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:27:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 19:47:41

US3392149

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:27:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
Data entry locked.	System	02 Sep 2020 19:47:41
User entered 'Day 2'	System	02 Sep 2020 19:47:41

US3392149

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:27:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-03T13:47:44', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '56831193-a9f6-429e-9458-cae6d228f313'	System	03 Sep 2020 18:48:07
User entered 'Does not interfere with activity (2)'	System	03 Sep 2020 18:48:07

US3392149

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:27:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-03T13:47:57', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '56831193-a9f6-429e-9458-cae6d228f313' User entered 'No (N)'	System	03 Sep 2020 18:48:07
	System	03 Sep 2020 18:48:07

US3392149

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:27:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-03T13:47:59', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '56831193-a9f6-429e-9458-cae6d228f313' User entered 'No (N)'	System	03 Sep 2020 18:48:07
	System	03 Sep 2020 18:48:07



US3392149

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:27:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-03T13:48:02', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '56831193-a9f6-429e-9458-cae6d228f313' User entered 'None (1)'	System	03 Sep 2020 18:48:07
	System	03 Sep 2020 18:48:07

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:27:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-03T13:48:05', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '56831193-a9f6-429e-9458-cae6d228f313' User entered '03 Sep 2020 13:48'	System	03 Sep 2020 18:48:07
	System	03 Sep 2020 18:48:07

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:27:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 19:47:41

US3392149

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:27:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 19:47:41

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
Data entry locked.	System	02 Sep 2020 19:47:41
User entered 'Day 3'	System	02 Sep 2020 19:47:41

US3392149

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:27:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-04T17:56:54', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '3ac431e8-35fc-401e-92b7-ec0272ad1c5b'	System	04 Sep 2020 22:57:08
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	04 Sep 2020 22:57:08

US3392149

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:27:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-04T17:56:57', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '3ac431e8-35fc-401e-92b7-ec0272ad1c5b' User entered 'No (N)'	System	04 Sep 2020 22:57:08
	System	04 Sep 2020 22:57:08

US3392149

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:27:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-04T17:57:00', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '3ac431e8-35fc-401e-92b7-ec0272ad1c5b' User entered 'No (N)'	System	04 Sep 2020 22:57:08
	System	04 Sep 2020 22:57:08



US3392149

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:27:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-04T17:57:03', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '3ac431e8-35fc-401e-92b7-ec0272ad1c5b' User entered 'None (1)'	System	04 Sep 2020 22:57:08
	System	04 Sep 2020 22:57:08

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:27:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-04T17:57:05', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '3ac431e8-35fc-401e-92b7-ec0272ad1c5b' User entered '04 Sep 2020 17:57'	System	04 Sep 2020 22:57:08
	System	04 Sep 2020 22:57:08

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:27:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 19:47:41

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:27:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 19:47:41

US3392149

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:27:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
Data entry locked.	System	02 Sep 2020 19:47:41
User entered 'Day 4'	System	02 Sep 2020 19:47:41

US3392149

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:27:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-05T19:27:48', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '1a0021a5-1e16-439d-9b99-8607bc5ce496' User entered 'None (1)'	System	06 Sep 2020 00:28:04
	System	06 Sep 2020 00:28:04

US3392149

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:27:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-05T19:27:51', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '1a0021a5-1e16-439d-9b99-8607bc5ce496' User entered 'No (N)'	System	06 Sep 2020 00:28:04
	System	06 Sep 2020 00:28:04

US3392149

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:27:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-05T19:27:53', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '1a0021a5-1e16-439d-9b99-8607bc5ce496' User entered 'No (N)'	System	06 Sep 2020 00:28:04
	System	06 Sep 2020 00:28:04



US3392149

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:27:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-05T19:27:56', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '1a0021a5-1e16-439d-9b99-8607bc5ce496' User entered 'None (1)'	System	06 Sep 2020 00:28:04
	System	06 Sep 2020 00:28:04

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:27:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-05T19:28:01', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '1a0021a5-1e16-439d-9b99-8607bc5ce496' User entered '05 Sep 2020 19:28'	System	06 Sep 2020 00:28:04
	System	06 Sep 2020 00:28:04

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:27:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 19:47:41

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:27:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 19:47:41

US3392149

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:27:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
Data entry locked.	System	02 Sep 2020 19:47:41
User entered 'Day 5'	System	02 Sep 2020 19:47:41

US3392149

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:27:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-06T17:37:18', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: 'b6131a83-d452-4dba-a40a-b67db59cc24a' User entered 'None (1)'	System	06 Sep 2020 22:37:29
	System	06 Sep 2020 22:37:29

US3392149

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:27:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-06T17:37:20', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: 'b6131a83-d452-4dba-a40a-b67db59cc24a' User entered 'No (N)'	System	06 Sep 2020 22:37:29
	System	06 Sep 2020 22:37:29

US3392149

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:27:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-06T17:37:22', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: 'b6131a83-d452-4dba-a40a-b67db59cc24a' User entered 'No (N)'	System	06 Sep 2020 22:37:29
	System	06 Sep 2020 22:37:29



US3392149

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:27:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-06T17:37:24', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: 'b6131a83-d452-4dba-a40a-b67db59cc24a' User entered 'None (1)'	System	06 Sep 2020 22:37:29
	System	06 Sep 2020 22:37:29

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:27:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-06T17:37:27', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: 'b6131a83-d452-4dba-a40a-b67db59cc24a' User entered '06 Sep 2020 17:37'	System	06 Sep 2020 22:37:29
	System	06 Sep 2020 22:37:29

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:27:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 19:47:41

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:27:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 19:47:41

US3392149

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:27:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
Data entry locked.	System	02 Sep 2020 19:47:41
User entered 'Day 6'	System	02 Sep 2020 19:47:41

US3392149

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:27:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-07T19:41:36', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: 'f7c79341-2859-4994-bf36-b6d5a5e2e7cc' User entered 'None (1)'	System	08 Sep 2020 00:41:48
	System	08 Sep 2020 00:41:48

US3392149

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:27:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-07T19:41:39', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: 'f7c79341-2859-4994-bf36-b6d5a5e2e7cc' User entered 'No (N)'	System	08 Sep 2020 00:41:48
	System	08 Sep 2020 00:41:48

US3392149

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:27:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-07T19:41:41', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: 'f7c79341-2859-4994-bf36-b6d5a5e2e7cc' User entered 'No (N)'	System	08 Sep 2020 00:41:48
	System	08 Sep 2020 00:41:48



US3392149

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:27:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-07T19:41:43', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: 'f7c79341-2859-4994-bf36-b6d5a5e2e7cc' User entered 'None (1)'	System	08 Sep 2020 00:41:48
	System	08 Sep 2020 00:41:48

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:27:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-07T19:41:46', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: 'f7c79341-2859-4994-bf36-b6d5a5e2e7cc' User entered '07 Sep 2020 19:41'	System	08 Sep 2020 00:41:48
	System	08 Sep 2020 00:41:48

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:27:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 19:47:41

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:27:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 19:47:41

US3392149

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:27:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
Data entry locked.	System	02 Sep 2020 19:47:41
User entered 'Day 7'	System	02 Sep 2020 19:47:41

US3392149

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:27:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-08T19:53:22', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '38f10f3d-9e01-4dd3-b4cc-556ad98f2e5c' User entered 'None (1)'	System	09 Sep 2020 00:53:36
	System	09 Sep 2020 00:53:36

US3392149

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:27:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-08T19:53:25', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '38f10f3d-9e01-4dd3-b4cc-556ad98f2e5c' User entered 'No (N)'	System	09 Sep 2020 00:53:36
	System	09 Sep 2020 00:53:36

US3392149

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:27:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-08T19:53:27', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '38f10f3d-9e01-4dd3-b4cc-556ad98f2e5c' User entered 'No (N)'	System	09 Sep 2020 00:53:36
	System	09 Sep 2020 00:53:36



US3392149

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:27:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-08T19:53:29', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '38f10f3d-9e01-4dd3-b4cc-556ad98f2e5c' User entered 'None (1)'	System	09 Sep 2020 00:53:36
	System	09 Sep 2020 00:53:36

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:27:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-08T19:53:31', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '38f10f3d-9e01-4dd3-b4cc-556ad98f2e5c' User entered '08 Sep 2020 19:53'	System	09 Sep 2020 00:53:36
	System	09 Sep 2020 00:53:36

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:27:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 19:47:41

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:27:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 19:47:41

US3392149

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:27:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
Data entry locked.	System	02 Sep 2020 19:47:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 19:47:41

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:27:05**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-02T15:17:23', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '9fb02f97-fa89-48a8-8f19-aa7ec84e2488' User entered 'None (0)'	System	02 Sep 2020 20:17:43
	System	02 Sep 2020 20:17:43

US3392149

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:27:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-02T15:17:25', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '9fb02f97-fa89-48a8-8f19-aa7ec84e2488' User entered 'None (0)'	System	02 Sep 2020 20:17:43
	System	02 Sep 2020 20:17:43

US3392149

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:27:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-02T15:17:29', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '9fb02f97-fa89-48a8-8f19-aa7ec84e2488' User entered 'None (0)'	System	02 Sep 2020 20:17:43
	System	02 Sep 2020 20:17:43



US3392149

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:27:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-02T15:17:31', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '9fb02f97-fa89-48a8-8f19-aa7ec84e2488' User entered 'None (0)'	System	02 Sep 2020 20:17:43
	System	02 Sep 2020 20:17:43

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:27:05**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-02T15:17:32', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '9fb02f97-fa89-48a8-8f19-aa7ec84e2488' User entered 'None (0)'	System	02 Sep 2020 20:17:43
	System	02 Sep 2020 20:17:43

US3392149

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:27:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-02T15:17:33', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '9fb02f97-fa89-48a8-8f19-aa7ec84e2488' User entered 'None (0)'	System	02 Sep 2020 20:17:43
	System	02 Sep 2020 20:17:43

US3392149

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:27:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-02T15:17:38', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '9fb02f97-fa89-48a8-8f19-aa7ec84e2488'	System	02 Sep 2020 20:17:43
User entered 'No (N)'	System	02 Sep 2020 20:17:43

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:27:05**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-02T15:17:40', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '9fb02f97-fa89-48a8-8f19-aa7ec84e2488' User entered '02 Sep 2020 15:17'	System	02 Sep 2020 20:17:43
	System	02 Sep 2020 20:17:43

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:27:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
User entered '02 Sep 2020 14:59'	System	02 Sep 2020 19:47:41

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:27:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
User entered '02 Sep 2020 17:29'	System	02 Sep 2020 19:47:41

US3392149

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:27:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
Data entry locked.	System	02 Sep 2020 19:47:41
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 19:47:41



US3392149

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:27:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-02T19:33:28', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '538fd303-2054-459a-b307-0f400704a269'	System	03 Sep 2020 00:34:22
User entered 'No interference with activity (1)'	System	03 Sep 2020 00:34:22

US3392149

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:27:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-02T19:33:42', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '538fd303-2054-459a-b307-0f400704a269'	System	03 Sep 2020 00:34:22
User entered 'Some interference with activity (2)'	System	03 Sep 2020 00:34:22

US3392149

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:27:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-02T19:33:50', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '538fd303-2054-459a-b307-0f400704a269'	System	03 Sep 2020 00:34:22
User entered 'No interference with activity (1)'	System	03 Sep 2020 00:34:22

US3392149

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:27:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-02T19:33:54', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '538fd303-2054-459a-b307-0f400704a269' User entered 'None (0)'	System	03 Sep 2020 00:34:22
	System	03 Sep 2020 00:34:22

US3392149

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:27:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-02T19:34:10', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '538fd303-2054-459a-b307-0f400704a269' User entered 'None (0)'	System	03 Sep 2020 00:34:22
	System	03 Sep 2020 00:34:22

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:27:05**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-02T19:34:13', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '538fd303-2054-459a-b307-0f400704a269'	System	03 Sep 2020 00:34:22
User entered 'No interference with activity (1)'	System	03 Sep 2020 00:34:22

US3392149

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:27:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-02T19:34:18', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '538fd303-2054-459a-b307-0f400704a269'	System	03 Sep 2020 00:34:22
User entered 'No (N)'	System	03 Sep 2020 00:34:22

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:27:05**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-02T19:34:20', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '538fd303-2054-459a-b307-0f400704a269' User entered '02 Sep 2020 19:34'	System	03 Sep 2020 00:34:22
	System	03 Sep 2020 00:34:22



**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:27:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
User entered '02 Sep 2020 18:24'	System	02 Sep 2020 19:47:41

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:27:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 19:47:41

US3392149

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:27:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
Data entry locked.	System	02 Sep 2020 19:47:41
User entered 'Day 2'	System	02 Sep 2020 19:47:41

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:27:05**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-03T13:48:09', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '81711a31-f2e9-40b9-b387-86ab1cfc73bd' User entered 'None (0)'	System	03 Sep 2020 18:48:53
	System	03 Sep 2020 18:48:53

US3392149

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:27:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-03T13:48:28', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '81711a31-f2e9-40b9-b387-86ab1cfc73bd' User entered 'No interference with activity (1)'	System	03 Sep 2020 18:48:53
	System	03 Sep 2020 18:48:53

US3392149

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:27:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-03T13:48:32', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '81711a31-f2e9-40b9-b387-86ab1cfc73bd' User entered 'None (0)'	System	03 Sep 2020 18:48:53
	System	03 Sep 2020 18:48:53

US3392149

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:27:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-03T13:48:35', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '81711a31-f2e9-40b9-b387-86ab1cfc73bd' User entered 'None (0)'	System	03 Sep 2020 18:48:53
	System	03 Sep 2020 18:48:53

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:27:05**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-03T13:48:40', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '81711a31-f2e9-40b9-b387-86ab1cfc73bd' User entered 'None (0)'	System	03 Sep 2020 18:48:53
	System	03 Sep 2020 18:48:53



**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:27:05**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-03T13:48:44', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '81711a31-f2e9-40b9-b387-86ab1cfc73bd' User entered 'No interference with activity (1)'	System	03 Sep 2020 18:48:53
	System	03 Sep 2020 18:48:53

US3392149

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:27:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-03T13:48:49', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '81711a31-f2e9-40b9-b387-86ab1cfc73bd' User entered 'No (N)'	System	03 Sep 2020 18:48:53
	System	03 Sep 2020 18:48:53

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:27:05**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-03T13:48:51', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '81711a31-f2e9-40b9-b387-86ab1cfc73bd' User entered '03 Sep 2020 13:48'	System	03 Sep 2020 18:48:53
	System	03 Sep 2020 18:48:53

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:27:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 19:47:41

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:27:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 19:47:41

US3392149

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:27:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
Data entry locked.	System	02 Sep 2020 19:47:41
User entered 'Day 3'	System	02 Sep 2020 19:47:41

US3392149

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:27:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-04T17:57:21', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '900f3447-2790-409d-85cf-d31ca0c06929'	System	04 Sep 2020 22:57:59
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	04 Sep 2020 22:57:59

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:27:05**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-04T17:57:26', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '900f3447-2790-409d-85cf-d31ca0c06929'	System	04 Sep 2020 22:57:59
User entered 'Some interference with activity (2)'	System	04 Sep 2020 22:57:59



US3392149

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:27:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-04T17:57:32', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '900f3447-2790-409d-85cf-d31ca0c06929' User entered 'None (0)'	System	04 Sep 2020 22:57:59
	System	04 Sep 2020 22:57:59

US3392149

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:27:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-04T17:57:34', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '900f3447-2790-409d-85cf-d31ca0c06929' User entered 'None (0)'	System	04 Sep 2020 22:57:59
	System	04 Sep 2020 22:57:59

US3392149

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:27:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-04T17:57:44', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '900f3447-2790-409d-85cf-d31ca0c06929'	System	04 Sep 2020 22:57:59
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	04 Sep 2020 22:57:59

US3392149

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:27:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-04T17:57:51', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '900f3447-2790-409d-85cf-d31ca0c06929'	System	04 Sep 2020 22:57:59
User entered 'No interference with activity (1)'	System	04 Sep 2020 22:57:59

US3392149

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:27:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-04T17:57:55', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '900f3447-2790-409d-85cf-d31ca0c06929' User entered 'No (N)'	System	04 Sep 2020 22:57:59
	System	04 Sep 2020 22:57:59

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:27:05**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-04T17:57:57', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '900f3447-2790-409d-85cf-d31ca0c06929' User entered '04 Sep 2020 17:57'	System	04 Sep 2020 22:57:59
	System	04 Sep 2020 22:57:59

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:27:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 19:47:41

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:27:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 19:47:41



US3392149

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:27:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
Data entry locked.	System	02 Sep 2020 19:47:41
User entered 'Day 4'	System	02 Sep 2020 19:47:41

US3392149

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:27:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-05T19:28:05', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '5ce9d35f-faae-490c-af26-ac69c4b05949' User entered 'None (0)'	System	06 Sep 2020 08:47:57
	System	06 Sep 2020 08:47:57

US3392149

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:27:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-05T19:28:08', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '5ce9d35f-faae-490c-af26-ac69c4b05949' User entered 'None (0)'	System	06 Sep 2020 08:47:57
	System	06 Sep 2020 08:47:57

US3392149

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:27:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-05T19:28:09', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '5ce9d35f-faae-490c-af26-ac69c4b05949' User entered 'None (0)'	System	06 Sep 2020 08:47:57
	System	06 Sep 2020 08:47:57

US3392149

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:27:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-05T19:28:11', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '5ce9d35f-faae-490c-af26-ac69c4b05949' User entered 'None (0)'	System	06 Sep 2020 08:47:57
	System	06 Sep 2020 08:47:57

US3392149

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:27:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-05T19:28:13', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '5ce9d35f-faae-490c-af26-ac69c4b05949' User entered 'None (0)'	System	06 Sep 2020 08:47:57
	System	06 Sep 2020 08:47:57

US3392149

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:27:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-05T19:28:15', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '5ce9d35f-faae-490c-af26-ac69c4b05949' User entered 'None (0)'	System	06 Sep 2020 08:47:57
	System	06 Sep 2020 08:47:57

US3392149

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:27:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-06T03:47:47', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '5ce9d35f-faae-490c-af26-ac69c4b05949' User entered 'No (N)'	System	06 Sep 2020 08:47:57
	System	06 Sep 2020 08:47:57



**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:27:05**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-06T03:47:51', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '5ce9d35f-faae-490c-af26-ac69c4b05949' User entered '06 Sep 2020 03:47'	System	06 Sep 2020 08:47:57
	System	06 Sep 2020 08:47:57

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:27:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 19:47:41

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:27:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 19:47:41

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
Data entry locked.	System	02 Sep 2020 19:47:41
User entered 'Day 5'	System	02 Sep 2020 19:47:41

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:27:05**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-06T17:37:37', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '3ee9d9fa-41dc-46c0-8976-1bc90f5cdb2c' User entered 'None (0)'	System	06 Sep 2020 22:37:54
	System	06 Sep 2020 22:37:54

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:27:05**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-06T17:37:39', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '3ee9d9fa-41dc-46c0-8976-1bc90f5cdb2c' User entered 'None (0)'	System	06 Sep 2020 22:37:54
	System	06 Sep 2020 22:37:54

US3392149

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:27:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-06T17:37:41', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '3ee9d9fa-41dc-46c0-8976-1bc90f5cdb2c' User entered 'None (0)'	System	06 Sep 2020 22:37:54
	System	06 Sep 2020 22:37:54

US3392149

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:27:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-06T17:37:42', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '3ee9d9fa-41dc-46c0-8976-1bc90f5cdb2c' User entered 'None (0)'	System	06 Sep 2020 22:37:54
	System	06 Sep 2020 22:37:54



**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:27:05**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-06T17:37:44', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '3ee9d9fa-41dc-46c0-8976-1bc90f5cdb2c' User entered 'None (0)'	System	06 Sep 2020 22:37:54
	System	06 Sep 2020 22:37:54

US3392149

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:27:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-06T17:37:45', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '3ee9d9fa-41dc-46c0-8976-1bc90f5cdb2c' User entered 'None (0)'	System	06 Sep 2020 22:37:54
	System	06 Sep 2020 22:37:54

US3392149

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:27:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-06T17:37:50', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '3ee9d9fa-41dc-46c0-8976-1bc90f5cdb2c' User entered 'No (N)'	System	06 Sep 2020 22:37:54
	System	06 Sep 2020 22:37:54

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:27:05**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-06T17:37:52', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '3ee9d9fa-41dc-46c0-8976-1bc90f5cdb2c' User entered '06 Sep 2020 17:37'	System	06 Sep 2020 22:37:54
	System	06 Sep 2020 22:37:54

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:27:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 19:47:41

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:27:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 19:47:41

US3392149

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:27:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
Data entry locked.	System	02 Sep 2020 19:47:41
User entered 'Day 6'	System	02 Sep 2020 19:47:41

US3392149

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:27:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-07T19:41:52', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '7fb556cf-a09f-4f95-84c6-781d7dc814f6' User entered 'None (0)'	System	08 Sep 2020 00:42:12
	System	08 Sep 2020 00:42:12



**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:27:05**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-07T19:41:54', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '7fb556cf-a09f-4f95-84c6-781d7dc814f6' User entered 'None (0)'	System	08 Sep 2020 00:42:12
	System	08 Sep 2020 00:42:12

US3392149

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:27:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-07T19:41:55', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '7fb556cf-a09f-4f95-84c6-781d7dc814f6' User entered 'None (0)'	System	08 Sep 2020 00:42:12
	System	08 Sep 2020 00:42:12

US3392149

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:27:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-07T19:41:57', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '7fb556cf-a09f-4f95-84c6-781d7dc814f6' User entered 'None (0)'	System	08 Sep 2020 00:42:12
	System	08 Sep 2020 00:42:12

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:27:05**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-07T19:41:58', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '7fb556cf-a09f-4f95-84c6-781d7dc814f6' User entered 'None (0)'	System	08 Sep 2020 00:42:12
	System	08 Sep 2020 00:42:12

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:27:05**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-07T19:42:00', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '7fb556cf-a09f-4f95-84c6-781d7dc814f6' User entered 'None (0)'	System	08 Sep 2020 00:42:12
	System	08 Sep 2020 00:42:12

US3392149

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:27:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-07T19:42:04', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '7fb556cf-a09f-4f95-84c6-781d7dc814f6'	System	08 Sep 2020 00:42:12
User entered 'No (N)'	System	08 Sep 2020 00:42:12

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:27:05**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-07T19:42:10', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '7fb556cf-a09f-4f95-84c6-781d7dc814f6' User entered '07 Sep 2020 19:42'	System	08 Sep 2020 00:42:12
	System	08 Sep 2020 00:42:12

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:27:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 19:47:41



**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:27:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 19:47:41

US3392149

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:27:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
Data entry locked.	System	02 Sep 2020 19:47:41
User entered 'Day 7'	System	02 Sep 2020 19:47:41

US3392149

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:27:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-08T19:53:35', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: 'c55c146e-a7ea-477b-b49e-a663e5a096b2' User entered 'None (0)'	System	09 Sep 2020 00:54:09
	System	09 Sep 2020 00:54:09

US3392149

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:27:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-08T19:53:37', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: 'c55c146e-a7ea-477b-b49e-a663e5a096b2' User entered 'None (0)'	System	09 Sep 2020 00:54:09
	System	09 Sep 2020 00:54:09

US3392149

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:27:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-08T19:53:38', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: 'c55c146e-a7ea-477b-b49e-a663e5a096b2' User entered 'None (0)'	System	09 Sep 2020 00:54:09
	System	09 Sep 2020 00:54:09

US3392149

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:27:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-08T19:53:43', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: 'c55c146e-a7ea-477b-b49e-a663e5a096b2' User entered 'None (0)'	System	09 Sep 2020 00:54:09
	System	09 Sep 2020 00:54:09

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:27:05**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-08T19:53:44', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: 'c55c146e-a7ea-477b-b49e-a663e5a096b2' User entered 'None (0)'	System	09 Sep 2020 00:54:09
	System	09 Sep 2020 00:54:09

US3392149

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:27:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-08T19:53:46', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: 'c55c146e-a7ea-477b-b49e-a663e5a096b2' User entered 'None (0)'	System	09 Sep 2020 00:54:09
	System	09 Sep 2020 00:54:09



US3392149

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:27:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-08T19:54:02', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: 'c55c146e-a7ea-477b-b49e-a663e5a096b2' User entered 'No (N)'	System	09 Sep 2020 00:54:09
	System	09 Sep 2020 00:54:09

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:27:05**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-09-08T19:54:04', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: 'c55c146e-a7ea-477b-b49e-a663e5a096b2' User entered '08 Sep 2020 19:54'	System	09 Sep 2020 00:54:09
	System	09 Sep 2020 00:54:09

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:27:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 19:47:41

**US3392149**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:27:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 19:47:41

US3392149

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:06:54
User closed query 'Per GCL Lab Recon: GCL has a swab sample with date of 12SEP2020. Please reconcile or clarify' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:08:22
Query 'Per GCL Lab Recon: GCL has a swab sample with date of 12SEP2020. Please reconcile or clarify' answered with 'UNSCHEDULED SAMPLE COLLECTED ON 12/SEP/2020 IS FOR COVID ILLNESS VISIT 1.' (Site from DM).	(b) (4), (b) (6)	31 Oct 2020 18:24:25
User opened query 'Per GCL Lab Recon: GCL has a swab sample with date of 12SEP2020. Please reconcile or clarify' (Site from DM).	(b) (4), (b) (6)	25 Oct 2020 15:15:31
User entered 'Yes (Y)'	Brenda Lawson (b) (4) (b) (4)	09 Sep 2020 23:38:51

**US3392149**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:06:54
User entered '9 Sep 2020'	Brenda Lawson (b) (4)	09 Sep 2020 23:38:51

**US3392149**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:27:05**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:06:54
User entered 'Contact Made (CONTACT MADE)'	Brenda Lawson (b) (4)	09 Sep 2020 23:38:51

**US3392149**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:27:05**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:06:54
User entered empty.	Brenda Lawson (b) (4)	09 Sep 2020 23:38:51



US3392149

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:06:54
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	09 Sep 2020 23:38:56

**US3392149**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:27:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User entered 'I'	System	09 Sep 2020 23:38:56

**US3392149**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:27:05**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:09
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:33:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:16:18

**US3392149**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:09
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:33:32
User entered '16 Sep 2020'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:16:18

**US3392149**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:27:05**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:09
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:33:32
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:16:18

**US3392149**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:27:05**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:09
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:33:32
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:16:18

**US3392149**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:09
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:33:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:16:22

**US3392149**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:27:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:09
User entered 'I'	System	20 Oct 2020 18:16:22



**US3392149**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:27:05**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:14:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:16:45

**US3392149**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:14:05
User entered '23 Sep 2020'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:16:45

**US3392149**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:27:05**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:14:05
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:16:45

**US3392149**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:27:05**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:14:05
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:16:45

**US3392149**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:14:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:16:49

**US3392149**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:27:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User entered 'I'	System	20 Oct 2020 18:16:49

US3392149

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:42:06
User closed query 'Per CDM: Was this visit performed? is "Yes". However, exposure is not recorded. Please confirm and reconcile. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 14:45:32
Query 'Per CDM: Was this visit performed? is "Yes". However, exposure is not recorded. Please confirm and reconcile. Thank you' answered with 'DATA UPDATED PER SOURCE DOCUMENTATION.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 22:01:02
User opened query 'Per CDM: Was this visit performed? is "Yes". However, exposure is not recorded. Please confirm and reconcile. Thank you' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 17:52:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 18:28:09

**US3392149**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:42:06
User entered '06 Oct 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:03:27
User entered '6 Oct 2020'	(b) (4), (b) (6)	20 Oct 2020 18:28:09



**US3392149**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:42:06
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:28:09

**US3392149**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:27:05**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User entered 'VISIT2'	System	20 Oct 2020 18:28:09

**US3392149**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:27:05**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	20 Oct 2020 18:30:03

**US3392149**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:27:05**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:42:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:30:03

**US3392149**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:42:06
User entered '06 Oct 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:03:39
User entered '6 Oct 2020'	(b) (4), (b) (6)	20 Oct 2020 18:30:03

**US3392149**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:42:06
User entered '10:17'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:30:03

**US3392149**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User entered '06 Oct 2020 10:17'	System	06 Nov 2020 22:03:39
User entered '6 Oct 2020 10:17'	System	20 Oct 2020 18:30:03

US3392149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:42:06
User entered '98.9' F	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:30:03



**US3392149**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:27:05**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:42:06
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:30:03

**US3392149**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:27:05**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:42:06
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:30:03

**US3392149**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:27:05**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:42:06
User entered '90'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:30:03

**US3392149**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:27:05**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User entered 'bpm'	System	20 Oct 2020 18:30:03

**US3392149**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:42:06
User entered '18'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:30:03

**US3392149**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:27:05**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User entered 'breaths/min'	System	20 Oct 2020 18:30:03

**US3392149**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:42:06
User entered '123'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:30:03

**US3392149**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:27:05**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User entered 'mmHg'	System	20 Oct 2020 18:30:03



**US3392149**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:42:06
User entered '92'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:30:03

**US3392149**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:27:05**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User entered 'mmHg'	System	20 Oct 2020 18:30:03

**US3392149**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:27:05**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	20 Oct 2020 18:30:03

US3392149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:42:06
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 18:05:15
User entered 'No (N)' reason for change: Data Entry Error	System	16 Nov 2020 18:05:15
User opened query 'Data is required. Please complete.' (Site from System).	Heather Salisbury (b) (4)	16 Nov 2020 18:05:15
User entered empty.	(b) (4)	
	System	20 Oct 2020 18:30:03
	(b) (4), (b) (6)	20 Oct 2020 18:30:03

**US3392149**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:27:05**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:42:06
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:30:03

**US3392149**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:42:06
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:30:03

**US3392149**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User entered empty.	System	20 Oct 2020 18:30:03

US3392149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:42:06
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:30:03



**US3392149**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:27:05**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:42:06
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:30:03

**US3392149**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:27:05**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:42:06
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:30:03

**US3392149**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:27:05**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:42:06
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:30:03

**US3392149**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:27:05**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User entered empty.	System	20 Oct 2020 18:30:03

**US3392149**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:42:06
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:30:03

US3392149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User entered empty.	System	20 Oct 2020 18:30:03

US3392149

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:42:06
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:30:03

**US3392149**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:27:05**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User entered empty.	System	20 Oct 2020 18:30:03



**US3392149**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:42:06
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:30:03

**US3392149**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:27:05**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User entered empty.	System	20 Oct 2020 18:30:03

**US3392149**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:27:05**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:42:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:28:31

US3392149

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:27:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:42:06
User entered '06 Oct 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:04:01
User entered '6 Oct 2020'	(b) (4), (b) (6)	20 Oct 2020 18:28:31

**US3392149**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:27:05**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:42:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:00:48

US3392149

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:05

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:42:06
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:00:48

US3392149

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:42:06
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:00:48

US3392149

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:05

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User entered empty.	System	06 Nov 2020 22:00:48



**US3392149**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:42:06
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:00:48

**US3392149**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:42:06
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:00:48

**US3392149**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User entered empty.	System	06 Nov 2020 22:00:48

**US3392149**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:42:06
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:00:48

US3392149

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User entered empty.	System	06 Nov 2020 22:00:48

**US3392149**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User entered empty.	System	06 Nov 2020 22:00:48

**US3392149**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:27:05**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:42:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:30:32

**US3392149**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:42:06
User entered '06 Oct 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:04:07
User entered '6 Oct 2020'	(b) (4), (b) (6)	20 Oct 2020 18:30:32



**US3392149**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:42:06
User entered '10:25'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:30:32

**US3392149**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User entered '06 Oct 2020 10:25'	System	06 Nov 2020 22:04:07
User entered '6 Oct 2020 10:25'	System	20 Oct 2020 18:30:32

US3392149

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:27:05

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:42:06
User entered '06 Oct 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:04:13
User entered '6 Oct 2020'	(b) (4), (b) (6)	20 Oct 2020 18:30:51

**US3392149**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:27:05**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	20 Oct 2020 18:30:51

**US3392149**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:27:05**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:42:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:30:51

**US3392149**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:42:06
User entered '10:23'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:30:51

**US3392149**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User entered '06 Oct 2020 10:23'	System	06 Nov 2020 22:04:13
User entered '6 Oct 2020 10:23'	System	20 Oct 2020 18:30:51

**US3392149**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:27:05**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	20 Oct 2020 18:30:51



**US3392149**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:27:05**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:42:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:30:51

**US3392149**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:42:06
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:30:51

**US3392149**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User entered empty.	System	20 Oct 2020 18:30:51

US3392149

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:42:06
User closed query 'Per GCL Lab Reconciliation: SWAB: Query response noted. However, swab sample collected on 12Sep2020 is note yet reported in the COVID diagnostic test under Covid-19 Assessment in EDC. Please enter the data on the appropriate visit.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Jan 2021 04:51:32
Query 'Per GCL Lab Reconciliation: SWAB: Query response noted. However, swab sample collected on 12Sep2020 is note yet reported in the COVID diagnostic test under Covid-19 Assessment in EDC. Please enter the data on the appropriate visit.' answered with 'DATA UPDATED. DATA ENTRY ERROR.' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 22:31:41
User opened query 'Per GCL Lab Reconciliation: SWAB: Query response noted. However, swab sample collected on 12Sep2020 is note yet reported in the COVID diagnostic test under Covid-19 Assessment in EDC. Please enter the data on the appropriate visit.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 07:42:30
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 12Sep2020 is reported under Illness Visit Day 1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 07:42:30
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 12Sep2020 is reported under Illness Visit Day 1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'UNSCHEDULED SAMPLE COLLECTED ON 12/SEP/2020 IS FOR COVID ILLNESS VISIT 1.' (Site from DM).	(b) (4), (b) (6)	31 Oct 2020 18:25:43

US3392149

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:05

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

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 12Sep2020 is reported under Illness Visit Day 1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. <br >' (Site from DM). User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 13:05:21 20 Oct 2020 18:18:45

**US3392149**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:27:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User entered 'I'	System	20 Oct 2020 18:18:45

**US3392149**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:27:05**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:57:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:26:07

**US3392149**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:57:41
User entered '13 Oct 2020'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:26:07



**US3392149**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:27:05**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:57:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:26:07

**US3392149**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:27:05**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:57:41
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:26:07

**US3392149**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:57:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:26:11

**US3392149**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:27:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User entered 'I'	System	20 Oct 2020 18:26:11

**US3392149**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:27:05**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:41:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:26:25

**US3392149**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:41:27
User entered '20 Oct 2020'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:26:25

**US3392149**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:27:05**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:41:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:26:25

**US3392149**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:27:05**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:41:27
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:26:25



**US3392149**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:41:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:26:28

**US3392149**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:27:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User entered 'I'	System	20 Oct 2020 18:26:28

**US3392149**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:27:05**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:24:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:01:40

**US3392149**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:24:05
User entered '27 Oct 2020'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:01:40

**US3392149**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:27:05**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:24:05
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:01:40

**US3392149**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:27:05**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:24:05
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:01:40

**US3392149**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:24:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:01:44

**US3392149**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:27:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User entered 'I'	System	27 Oct 2020 18:01:44



**US3392149**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:27:05**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:23:33
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	02 Nov 2020 16:49:24

**US3392149**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:23:33
User entered '2 Nov 2020'	Brenda Lawson (b) (4)	02 Nov 2020 16:49:24

**US3392149**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:23:33
User entered 'Clinic (Clinic)'	Brenda Lawson (b) (4)	02 Nov 2020 16:49:24

**US3392149**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:27:05**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User entered 'VISIT3'	System	02 Nov 2020 16:49:24

**US3392149**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:27:05**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:23:33
User entered 'No (N)'	Brenda Lawson (b) (4)	02 Nov 2020 16:49:31

US3392149

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:23:33
User entered empty.	Brenda Lawson (b) (4)	02 Nov 2020 16:49:31

US3392149

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:23:33
User entered empty.	Brenda Lawson (b) (4)	02 Nov 2020 16:49:31

**US3392149**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User entered empty.	System	02 Nov 2020 16:49:31



US3392149

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:23:33
User entered empty.	Brenda Lawson (b) (4)	02 Nov 2020 16:49:31

US3392149

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:23:33
User entered empty.	Brenda Lawson (b) (4)	02 Nov 2020 16:49:31

**US3392149**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:27:05**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:23:33
User entered empty.	Brenda Lawson (b) (4)	02 Nov 2020 16:49:31

**US3392149**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:27:05**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:23:33
User entered empty.	Brenda Lawson (b) (4)	02 Nov 2020 16:49:31

**US3392149**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:27:05**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User entered empty.	System	02 Nov 2020 16:49:31

US3392149

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:23:33
User entered empty.	Brenda Lawson (b) (4)	02 Nov 2020 16:49:31

US3392149

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User entered empty.	System	02 Nov 2020 16:49:31

US3392149

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:23:33
User entered empty.	Brenda Lawson (b) (4)	02 Nov 2020 16:49:31



**US3392149**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:27:05**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User entered empty.	System	02 Nov 2020 16:49:31

**US3392149**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:23:33
User entered empty.	Brenda Lawson (b) (4)	02 Nov 2020 16:49:31

**US3392149**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:27:05**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User entered empty.	System	02 Nov 2020 16:49:31

**US3392149**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:27:05**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17

**US3392149**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:27:05**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17

**US3392149**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:27:05**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:23:33
User entered 'No (N)'	Brenda Lawson (b) (4)	02 Nov 2020 16:49:40

US3392149

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:27:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:23:33
User entered empty.	Brenda Lawson (b) (4)	02 Nov 2020 16:49:40

US3392149

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:27:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:23:33
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	02 Nov 2020 16:50:04



US3392149

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:27:05

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:23:33
User entered '02 Nov 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:05:27
User entered '2 Nov 2020'	Brenda Lawson (b) (4) (b) (4)	02 Nov 2020 16:50:04

**US3392149**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:23:33
User entered '10:20'	Brenda Lawson (b) (4)	02 Nov 2020 16:50:04

**US3392149**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User entered '02 Nov 2020 10:20'	System	06 Nov 2020 22:05:27
User entered '2 Nov 2020 10:20'	System	02 Nov 2020 16:50:04

US3392149

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:23:33
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	02 Nov 2020 16:50:08

**US3392149**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:27:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User entered 'I'	System	02 Nov 2020 16:50:08

US3392149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
Data entry locked.	System	02 Sep 2020 19:47:41
User entered 'Day 64'	System	02 Sep 2020 19:47:41

**US3392149**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[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 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-11-02T18:03:37', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: 'bbb74c99-1609-4dc9-9b7e-c8c0ed7749e9' User entered 'No (N)'	System	03 Nov 2020 00:04:43
	System	03 Nov 2020 00:04:43

**US3392149**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Have you been exposed to someone with 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 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-11-02T18:04:34', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: 'bbb74c99-1609-4dc9-9b7e-c8c0ed7749e9' User entered 'No (N)'	System	03 Nov 2020 00:04:43
	System	03 Nov 2020 00:04:43



**US3392149**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-11-02T18:04:39', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: 'bbb74c99-1609-4dc9-9b7e-c8c0ed7749e9' User entered '02 Nov 2020 18:04:39'	System	03 Nov 2020 00:04:43
	System	03 Nov 2020 00:04:43

**US3392149**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
Data entry locked.	System	02 Sep 2020 19:47:41
User entered '02 Nov 2020 00:01'	System	02 Sep 2020 19:47:41

**US3392149**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
Data entry locked.	System	02 Sep 2020 19:47:41
User entered '06 Nov 2020 23:59'	System	02 Sep 2020 19:47:41

**US3392149**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
Data entry locked.	System	02 Sep 2020 19:47:41
User entered 'Day 71'	System	02 Sep 2020 19:47:41

**US3392149**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[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 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-11-09T05:40:57', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '66266ed7-7bc2-46f7-8297-89a3a71e18ae' User entered 'No (N)'	System	09 Nov 2020 11:41:19
	System	09 Nov 2020 11:41:19

**US3392149**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Have you been exposed to someone with 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 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-11-09T05:41:08', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '66266ed7-7bc2-46f7-8297-89a3a71e18ae' User entered 'No (N)'	System	09 Nov 2020 11:41:19
	System	09 Nov 2020 11:41:19

**US3392149**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-11-09T05:41:13', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '66266ed7-7bc2-46f7-8297-89a3a71e18ae' User entered '09 Nov 2020 05:41:13'	System	09 Nov 2020 11:41:19
	System	09 Nov 2020 11:41:19

**US3392149**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
Data entry locked.	System	02 Sep 2020 19:47:41
User entered '09 Nov 2020 00:01'	System	02 Sep 2020 19:47:41



**US3392149**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
Data entry locked.	System	02 Sep 2020 19:47:41
User entered '13 Nov 2020 23:59'	System	02 Sep 2020 19:47:41

**US3392149**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
Data entry locked.	System	02 Sep 2020 19:47:41
User entered 'Day 78'	System	02 Sep 2020 19:47:41

US3392149

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:05

[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 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-11-16T04:49:17', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '3590dec3-4513-4b12-abee-95d7698ceb6f' User entered 'No (N)'	System	16 Nov 2020 10:49:34
	System	16 Nov 2020 10:49:34

**US3392149**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Have you been exposed to someone with 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 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-11-16T04:49:28', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '3590dec3-4513-4b12-abee-95d7698ceb6f' User entered 'No (N)'	System	16 Nov 2020 10:49:34
	System	16 Nov 2020 10:49:34

**US3392149**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-11-16T04:49:32', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '3590dec3-4513-4b12-abee-95d7698ceb6f' User entered '16 Nov 2020 04:49:32'	System	16 Nov 2020 10:49:34
	System	16 Nov 2020 10:49:34

**US3392149**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
Data entry locked.	System	02 Sep 2020 19:47:41
User entered '16 Nov 2020 00:01'	System	02 Sep 2020 19:47:41

**US3392149**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:39:24
Data entry locked.	System	02 Sep 2020 19:47:41
User entered '20 Nov 2020 23:59'	System	02 Sep 2020 19:47:41

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 02:49:36



**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '20 Nov 2020 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '24 Nov 2020 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[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 (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-11-30T04:48:26', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: 'ca3af091-8cc7-42b7-8827-7e5b125d2d41' User entered 'No (N)'	System	30 Nov 2020 10:48:38

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Have you been exposed to someone with 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 (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-11-30T04:48:29', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: 'ca3af091-8cc7-42b7-8827-7e5b125d2d41'	System	30 Nov 2020 10:48:38
User entered 'No (N)'	System	30 Nov 2020 10:48:38

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-11-30T04:48:36', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: 'ca3af091-8cc7-42b7-8827-7e5b125d2d41' User entered '30 Nov 2020 04:48:36'	System	30 Nov 2020 10:48:38
	System	30 Nov 2020 10:48:38

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '27 Nov 2020 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '01 Dec 2020 23:59'	System	20 Nov 2020 02:49:36



**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[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 (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-12-04T04:54:23', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '48abf2da-3274-436a-9c9a-72499bb33d87' User entered 'No (N)'	System	04 Dec 2020 10:54:35
	System	04 Dec 2020 10:54:35

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Have you been exposed to someone with 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 (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-12-04T04:54:28', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '48abf2da-3274-436a-9c9a-72499bb33d87' User entered 'No (N)'	System	04 Dec 2020 10:54:35
	System	04 Dec 2020 10:54:35

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-12-04T04:54:32', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '48abf2da-3274-436a-9c9a-72499bb33d87' User entered '04 Dec 2020 04:54:32'	System	04 Dec 2020 10:54:35
	System	04 Dec 2020 10:54:35

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '04 Dec 2020 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '08 Dec 2020 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[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 (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-12-11T06:08:12', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: 'e4ddb6aa-d233-4334-9372-4b2af318370f' User entered 'No (N)'	System	11 Dec 2020 12:08:26
	System	11 Dec 2020 12:08:26



**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Have you been exposed to someone with 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 (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-12-11T06:08:17', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: 'e4ddb6aa-d233-4334-9372-4b2af318370f' User entered 'No (N)'	System	11 Dec 2020 12:08:26
	System	11 Dec 2020 12:08:26

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-12-11T06:08:24', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: 'e4ddb6aa-d233-4334-9372-4b2af318370f' User entered '11 Dec 2020 06:08:24'	System	11 Dec 2020 12:08:26
	System	11 Dec 2020 12:08:26

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '11 Dec 2020 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '15 Dec 2020 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[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 (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-12-20T17:41:05', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: 'c72a89ab-0873-4fca-8b8f-ce058ed4a894' User entered 'No (N)'	System	20 Dec 2020 23:41:16
	System	20 Dec 2020 23:41:16

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Have you been exposed to someone with 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 (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-12-20T17:41:07', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: 'c72a89ab-0873-4fca-8b8f-ce058ed4a894'	System	20 Dec 2020 23:41:16
User entered 'No (N)'	System	20 Dec 2020 23:41:16

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-12-20T17:41:12', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: 'c72a89ab-0873-4fca-8b8f-ce058ed4a894'	System	20 Dec 2020 23:41:16
User entered '20 Dec 2020 17:41:12'	System	20 Dec 2020 23:41:16



**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[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 (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-12-25T04:34:10', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '1a648a9a-af12-416f-a304-c95357d3eca7' User entered 'No (N)'	System	25 Dec 2020 10:34:20
	System	25 Dec 2020 10:34:20

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Have you been exposed to someone with 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 (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-12-25T04:34:13', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '1a648a9a-af12-416f-a304-c95357d3eca7'	System	25 Dec 2020 10:34:20
User entered 'No (N)'	System	25 Dec 2020 10:34:20

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2020-12-25T04:34:18', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '1a648a9a-af12-416f-a304-c95357d3eca7' User entered '25 Dec 2020 04:34:18'	System	25 Dec 2020 10:34:20
	System	25 Dec 2020 10:34:20

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 02:49:36



**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[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 (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2021-01-03T12:06:52', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '128ad520-4719-40ce-9722-4a06bf0168f7' User entered 'No (N)'	System	11 Jan 2021 09:20:22
	System	11 Jan 2021 09:20:22

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Have you been exposed to someone with 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 (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2021-01-03T12:06:55', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '128ad520-4719-40ce-9722-4a06bf0168f7' User entered 'No (N)'	System	11 Jan 2021 09:20:22
	System	11 Jan 2021 09:20:22

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2021-01-03T12:07:00', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '128ad520-4719-40ce-9722-4a06bf0168f7' User entered '03 Jan 2021 12:07:00'	System	11 Jan 2021 09:20:22
	System	11 Jan 2021 09:20:22

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[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 (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2021-01-08T05:59:55', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '3ff6367c-2678-41ca-9069-4f9b631f2ed4' User entered 'No (N)'	System	11 Jan 2021 09:20:22
	System	11 Jan 2021 09:20:22



**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

Have you been exposed to someone with 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 (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2021-01-08T06:00:02', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '3ff6367c-2678-41ca-9069-4f9b631f2ed4'	System	11 Jan 2021 09:20:22
User entered 'No (N)'	System	11 Jan 2021 09:20:22

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2021-01-08T06:00:08', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '3ff6367c-2678-41ca-9069-4f9b631f2ed4' User entered '08 Jan 2021 06:00:08'	System	11 Jan 2021 09:20:22
	System	11 Jan 2021 09:20:22

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[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 (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2021-01-15T05:32:33', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '0de1efe4-6d5c-40dd-a6d7-3c1f2dcafd85'	System	15 Jan 2021 11:32:45
User entered 'No (N)'	System	15 Jan 2021 11:32:45

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

Have you been exposed to someone with 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 (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2021-01-15T05:32:38', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '0de1efe4-6d5c-40dd-a6d7-3c1f2dcafd85'	System	15 Jan 2021 11:32:45
User entered 'No (N)'	System	15 Jan 2021 11:32:45

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2021-01-15T05:32:42', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '0de1efe4-6d5c-40dd-a6d7-3c1f2dcafd85' User entered '15 Jan 2021 05:32:42'	System	15 Jan 2021 11:32:45
	System	15 Jan 2021 11:32:45



**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[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 (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2021-01-22T06:28:50', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: 'e3183226-5b13-40ad-80e7-7c82ca52aebc' User entered 'No (N)'	System	22 Jan 2021 12:29:20
	System	22 Jan 2021 12:29:20

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

Have you been exposed to someone with 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 (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2021-01-22T06:29:08', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: 'e3183226-5b13-40ad-80e7-7c82ca52aebc'	System	22 Jan 2021 12:29:20
User entered 'No (N)'	System	22 Jan 2021 12:29:20

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2021-01-22T06:29:16', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: 'e3183226-5b13-40ad-80e7-7c82ca52aebc' User entered '22 Jan 2021 06:29:16'	System	22 Jan 2021 12:29:20
	System	22 Jan 2021 12:29:20

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 02:49:36



**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[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 (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2021-01-29T06:57:45', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: 'c17b3589-fa54-4910-b79c-a4533276b53a' User entered 'No (N)'	System	29 Jan 2021 12:57:58
	System	29 Jan 2021 12:57:58

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

Have you been exposed to someone with 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 (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2021-01-29T06:57:48', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: 'c17b3589-fa54-4910-b79c-a4533276b53a' User entered 'No (N)'	System	29 Jan 2021 12:57:58
	System	29 Jan 2021 12:57:58

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D286709F-FFF7-4849-965C-5D4E9B568AE4)', Time: '2021-01-29T06:57:54', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: 'c17b3589-fa54-4910-b79c-a4533276b53a' User entered '29 Jan 2021 06:57:54'	System	29 Jan 2021 12:57:58
	System	29 Jan 2021 12:57:58

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 02:49:36



**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 02:49:36



**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[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 (D87855FE-43CD-47A0-9D98-7BBC4D2D12C2)', Time: '2021-03-02T09:11:09-06:00', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '899de5ad-3712-4dc6-9aa9-7bd9c68c738b' User entered 'No (N)'	System	02 Mar 2021 15:11:18
	System	02 Mar 2021 15:11:18

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

Have you been exposed to someone with 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 (D87855FE-43CD-47A0-9D98-7BBC4D2D12C2)', Time: '2021-03-02T09:11:12-06:00', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '899de5ad-3712-4dc6-9aa9-7bd9c68c738b' User entered 'No (N)'	System	02 Mar 2021 15:11:18
	System	02 Mar 2021 15:11:18

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D87855FE-43CD-47A0-9D98-7BBC4D2D12C2)', Time: '2021-03-02T09:11:15-06:00', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '899de5ad-3712-4dc6-9aa9-7bd9c68c738b' User entered '02 Mar 2021 09:11:15'	System	02 Mar 2021 15:11:18
	System	02 Mar 2021 15:11:18

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[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 (D87855FE-43CD-47A0-9D98-7BBC4D2D12C2)', Time: '2021-03-07T12:00:58-06:00', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '79c514ef-67ae-4c8b-b16c-383ede0184a4'	System	07 Mar 2021 18:01:45
User entered 'No (N)'	System	07 Mar 2021 18:01:45

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

Have you been exposed to someone with 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 (D87855FE-43CD-47A0-9D98-7BBC4D2D12C2)', Time: '2021-03-07T12:01:01-06:00', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '79c514ef-67ae-4c8b-b16c-383ede0184a4'	System	07 Mar 2021 18:01:45
User entered 'No (N)'	System	07 Mar 2021 18:01:45



**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D87855FE-43CD-47A0-9D98-7BBC4D2D12C2)', Time: '2021-03-07T12:01:03-06:00', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '79c514ef-67ae-4c8b-b16c-383ede0184a4' User entered '07 Mar 2021 12:01:03'	System	07 Mar 2021 18:01:45
	System	07 Mar 2021 18:01:45

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[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 (D87855FE-43CD-47A0-9D98-7BBC4D2D12C2)', Time: '2021-03-12T09:48:55-06:00', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '29ab2199-1ff5-45d9-b1c4-1889c71184a4'	System	12 Mar 2021 15:49:08
User entered 'No (N)'	System	12 Mar 2021 15:49:08

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

Have you been exposed to someone with 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 (D87855FE-43CD-47A0-9D98-7BBC4D2D12C2)', Time: '2021-03-12T09:48:58-06:00', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '29ab2199-1ff5-45d9-b1c4-1889c71184a4'	System	12 Mar 2021 15:49:08
User entered 'No (N)'	System	12 Mar 2021 15:49:08

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D87855FE-43CD-47A0-9D98-7BBC4D2D12C2)', Time: '2021-03-12T09:49:04-06:00', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '29ab2199-1ff5-45d9-b1c4-1889c71184a4'	System	12 Mar 2021 15:49:08
User entered '12 Mar 2021 09:49:04'	System	12 Mar 2021 15:49:08

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 02:49:36



**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[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 (D87855FE-43CD-47A0-9D98-7BBC4D2D12C2)', Time: '2021-03-19T06:28:41-05:00', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '57b1a851-8197-4eb8-82fa-d5612d2d1f7d'	System	19 Mar 2021 11:28:52
User entered 'No (N)'	System	19 Mar 2021 11:28:52

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

Have you been exposed to someone with 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 (D87855FE-43CD-47A0-9D98-7BBC4D2D12C2)', Time: '2021-03-19T06:28:44-05:00', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '57b1a851-8197-4eb8-82fa-d5612d2d1f7d'	System	19 Mar 2021 11:28:52
User entered 'No (N)'	System	19 Mar 2021 11:28:52

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D87855FE-43CD-47A0-9D98-7BBC4D2D12C2)', Time: '2021-03-19T06:28:49-05:00', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '57b1a851-8197-4eb8-82fa-d5612d2d1f7d' User entered '19 Mar 2021 06:28:49'	System	19 Mar 2021 11:28:52
	System	19 Mar 2021 11:28:52

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 02:49:36



**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[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 (D87855FE-43CD-47A0-9D98-7BBC4D2D12C2)', Time: '2021-03-26T05:24:11-05:00', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: 'f6584654-d7cd-4d58-9159-099ee53f2578'	System	26 Mar 2021 10:24:19
User entered 'No (N)'	System	26 Mar 2021 10:24:19

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

Have you been exposed to someone with 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 (D87855FE-43CD-47A0-9D98-7BBC4D2D12C2)', Time: '2021-03-26T05:24:14-05:00', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: 'f6584654-d7cd-4d58-9159-099ee53f2578'	System	26 Mar 2021 10:24:19
User entered 'No (N)'	System	26 Mar 2021 10:24:19

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D87855FE-43CD-47A0-9D98-7BBC4D2D12C2)', Time: '2021-03-26T05:24:17-05:00', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: 'f6584654-d7cd-4d58-9159-099ee53f2578' User entered '26 Mar 2021 05:24:17'	System	26 Mar 2021 10:24:19
	System	26 Mar 2021 10:24:19

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[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 (D87855FE-43CD-47A0-9D98-7BBC4D2D12C2)', Time: '2021-04-02T05:58:06-05:00', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '0c6a9e68-8a43-4498-9297-f42f82d837b8' User entered 'No (N)'	System	02 Apr 2021 10:58:22
	System	02 Apr 2021 10:58:22

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

Have you been exposed to someone with 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 (D87855FE-43CD-47A0-9D98-7BBC4D2D12C2)', Time: '2021-04-02T05:58:12-05:00', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '0c6a9e68-8a43-4498-9297-f42f82d837b8' User entered 'No (N)'	System	02 Apr 2021 10:58:22
	System	02 Apr 2021 10:58:22



**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D87855FE-43CD-47A0-9D98-7BBC4D2D12C2)', Time: '2021-04-02T05:58:18-05:00', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '0c6a9e68-8a43-4498-9297-f42f82d837b8' User entered '02 Apr 2021 05:58:18'	System	02 Apr 2021 10:58:22
	System	02 Apr 2021 10:58:22

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[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 (D87855FE-43CD-47A0-9D98-7BBC4D2D12C2)', Time: '2021-04-11T12:12:32-05:00', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '24007cd5-0f77-4aa5-91cd-01b6561b37ba' User entered 'No (N)'	System	11 Apr 2021 17:12:40
	System	11 Apr 2021 17:12:40

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

Have you been exposed to someone with 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 (D87855FE-43CD-47A0-9D98-7BBC4D2D12C2)', Time: '2021-04-11T12:12:35-05:00', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '24007cd5-0f77-4aa5-91cd-01b6561b37ba' User entered 'No (N)'	System	11 Apr 2021 17:12:40
	System	11 Apr 2021 17:12:40

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D87855FE-43CD-47A0-9D98-7BBC4D2D12C2)', Time: '2021-04-11T12:12:38-05:00', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '24007cd5-0f77-4aa5-91cd-01b6561b37ba' User entered '11 Apr 2021 12:12:38'	System	11 Apr 2021 17:12:40
	System	11 Apr 2021 17:12:40

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 02:49:36



**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[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 (D87855FE-43CD-47A0-9D98-7BBC4D2D12C2)', Time: '2021-04-16T17:10:43-05:00', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '4441c09d-8ba9-4b1c-8715-19d7a2e17e59' User entered 'No (N)'	System	16 Apr 2021 22:10:50
	System	16 Apr 2021 22:10:50

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

Have you been exposed to someone with 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 (D87855FE-43CD-47A0-9D98-7BBC4D2D12C2)', Time: '2021-04-16T17:10:45-05:00', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '4441c09d-8ba9-4b1c-8715-19d7a2e17e59' User entered 'No (N)'	System	16 Apr 2021 22:10:50
	System	16 Apr 2021 22:10:50

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D87855FE-43CD-47A0-9D98-7BBC4D2D12C2)', Time: '2021-04-16T17:10:48-05:00', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '4441c09d-8ba9-4b1c-8715-19d7a2e17e59' User entered '16 Apr 2021 17:10:48'	System	16 Apr 2021 22:10:50
	System	16 Apr 2021 22:10:50

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 02:49:36



**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[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 (D87855FE-43CD-47A0-9D98-7BBC4D2D12C2)', Time: '2021-04-26T06:32:09-05:00', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '70b75ab7-8a83-40e4-9ced-cce9a03e6af1' User entered 'Yes (Y)'	System	26 Apr 2021 11:33:34
	System	26 Apr 2021 11:33:34

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

Have you been exposed to someone with 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 (D87855FE-43CD-47A0-9D98-7BBC4D2D12C2)', Time: '2021-04-26T06:30:40-05:00', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '70b75ab7-8a83-40e4-9ced-cce9a03e6af1' User entered 'No (N)'	System	26 Apr 2021 11:33:34

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[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 (D87855FE-43CD-47A0-9D98-7BBC4D2D12C2)', Time: '2021-04-26T06:32:16-05:00', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '70b75ab7-8a83-40e4-9ced-cce9a03e6af1' User entered 'No (N)'	System	26 Apr 2021 11:33:34
	System	26 Apr 2021 11:33:34

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[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 (D87855FE-43CD-47A0-9D98-7BBC4D2D12C2)', Time: '2021-04-26T06:33:07-05:00', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '70b75ab7-8a83-40e4-9ced-cce9a03e6af1'	System	26 Apr 2021 11:33:34
User entered 'Yes (Y)'	System	26 Apr 2021 11:33:34

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Please 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 (D87855FE-43CD-47A0-9D98-7BBC4D2D12C2)', Time: '2021-04-26T06:33:18-05:00', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '70b75ab7-8a83-40e4-9ced-cce9a03e6af1'	System	26 Apr 2021 11:33:34
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	26 Apr 2021 11:33:34

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D87855FE-43CD-47A0-9D98-7BBC4D2D12C2)', Time: '2021-04-26T06:33:23-05:00', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: '70b75ab7-8a83-40e4-9ced-cce9a03e6af1' User entered '26 Apr 2021 06:33:23'	System	26 Apr 2021 11:33:34
	System	26 Apr 2021 11:33:34

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 02:49:36



**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 02:49:36



**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 02:49:36



**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 02:49:36



**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 02:49:36



**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 02:49:36



**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 02:49:36



**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 02:49:36



**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 02:49:36



**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 02:49:36



**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 02:49:36



**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 02:49:36



**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 02:49:36



**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 02:49:36



**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 02:49:36



**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 02:49:36



**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 02:49:36



**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 02:49:36



**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 02:49:36



**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 02:49:36



**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 02:49:36



**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 02:49:36



**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 02:49:36



**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 02:49:36



**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 02:49:36



**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 02:49:36



**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 02:49:36



**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 02:49:36



**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 02:49:36



**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 02:49:36



**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 02:49:36

**US3392149**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:27:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:49:36
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 02:49:36



US3392149

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:27:05

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 07:43:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D87855FE-43CD-47A0-9D98-7BBC4D2D12C2)', Time: '2021-03-02T09:11:00-06:00', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: 'ea4c89e8-fc15-4d41-8b13-dd452e6d440b'	System	02 Mar 2021 15:11:10
User entered 'No (N)'	System	02 Mar 2021 15:11:10

**US3392149**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 17:27:05**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:43:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D87855FE-43CD-47A0-9D98-7BBC4D2D12C2)', Time: '2021-03-02T09:11:04-06:00', User OID: 'PatientReportedOutcome (US3392149)', ODM File OID: 'ea4c89e8-fc15-4d41-8b13-dd452e6d440b' User entered '02 Mar 2021 09:11:04'	System	02 Mar 2021 15:11:10
	System	02 Mar 2021 15:11:10

**US3392149**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:27:05**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	08 Mar 2021 22:57:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Nov 2020 18:28:25

**US3392149**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	08 Mar 2021 22:57:34
User entered '30 Nov 2020'	(b) (4) (b) (4), (b) (6)	30 Nov 2020 18:28:25

**US3392149**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:27:05**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	08 Mar 2021 22:57:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	30 Nov 2020 18:28:25

**US3392149**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:27:05**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	08 Mar 2021 22:57:34
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 18:28:25

**US3392149**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User signature succeeded.	Michael Cotugno (b) (4)	08 Mar 2021 22:57:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Nov 2020 18:28:31

**US3392149**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:27:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 09:31:17
User entered 'I'	System	30 Nov 2020 18:28:31



**US3392149**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:27:05**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:40:34
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered 'Yes (Y)'	Heather Salisbury (b) (4)	22 Dec 2020 16:38:06

**US3392149**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:40:34
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered '22 Dec 2020'	Heather Salisbury (b) (4)	22 Dec 2020 16:38:06

**US3392149**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:27:05**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:40:34
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered 'Contact Made (CONTACT MADE)'	Heather Salisbury (b) (4)	22 Dec 2020 16:38:06

**US3392149**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:27:05**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:40:34
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered empty.	Heather Salisbury (b) (4)	22 Dec 2020 16:38:06

**US3392149**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:40:34
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered 'Yes (Y)'	Heather Salisbury (b) (4)	22 Dec 2020 16:38:10

**US3392149**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:27:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:40:34
User entered 'I'	System	22 Dec 2020 16:38:10

**US3392149**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:27:05**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:01:07
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:32:47

**US3392149**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:01:07
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered '01 Feb 2021'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:32:47



**US3392149**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:27:05**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:01:07
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:32:47

**US3392149**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:27:05**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:01:07
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:32:47

**US3392149**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:01:07
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 21:32:58

**US3392149**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:27:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:01:07
User entered 'I'	System	05 Feb 2021 21:32:58

**US3392149**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:27:05**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:03:07
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered 'Yes (Y)'	Heather Salisbury (b) (4)	02 Mar 2021 15:39:19

**US3392149**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:03:07
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered '02 Mar 2021'	Heather Salisbury (b) (4)	02 Mar 2021 15:39:19

**US3392149**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:27:05**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:03:07
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered 'Contact Made (CONTACT MADE)'	Heather Salisbury (b) (4)	02 Mar 2021 15:39:19

**US3392149**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:27:05**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:03:07
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered empty.	Heather Salisbury (b) (4)	02 Mar 2021 15:39:19



**US3392149**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:03:07
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered 'Yes (Y)'	Heather Salisbury (b) (4)	02 Mar 2021 15:39:23

**US3392149**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:27:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:03:07
User entered 'I'	System	02 Mar 2021 15:39:23

**US3392149**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:27:05**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:32
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 20:02:53

**US3392149**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:32
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered '22 Mar 2021'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 20:02:53

**US3392149**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:27:05**

[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 14:14:32
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 20:02:53

**US3392149**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:27:05**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:32
User entered 'VISIT4'	System	22 Mar 2021 20:02:53

**US3392149**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:27:05**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:32
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 20:02:56

**US3392149**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:27:05**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:32
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 20:02:56



**US3392149**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:27:05**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:32
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 20:03:07

US3392149

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:27:05

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:32
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered '22 Mar 2021'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 20:03:07

**US3392149**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:32
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered '12:16'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 20:03:07

**US3392149**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:32
User entered '22 Mar 2021 12:16'	System	22 Mar 2021 20:03:07

**US3392149**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:32
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 20:03:10

**US3392149**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:27:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:32
User entered 'I'	System	22 Mar 2021 20:03:10

**US3392149**

**Folder: Covid-19 Assessment 12 Sep 2020**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 17:27:05**

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered '12 Sep 2020'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 22:30:18

**US3392149**

**Folder: Covid-19 Assessment 12 Sep 2020**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 17:27:05**

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered '12:00'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 22:30:18



**US3392149**

**Folder: Covid-19 Assessment 12 Sep 2020**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 17:27:05**

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User entered '12 Sep 2020 12:00'	System	04 Jan 2021 22:30:18

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:27:05

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 22:30:18

**US3392149**

**Folder: Covid-19 Assessment 12 Sep 2020**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 17:27:05**

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 22:30:18

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Day 1 (Day 1)'	(b) (4)	25 Jan 2021 23:51:43

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered '11 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Brandon Illickal (b) (4)	25 Jan 2021 23:56:52
User entered '12 Sep 2020'	(b) (4)	
	Brandon Illickal (b) (4)	25 Jan 2021 23:51:43
	(b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered '0'	(b) (4)	25 Jan 2021 23:51:43

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered '98'	(b) (4)	25 Jan 2021 23:51:43

**US3392149**

**Folder: Covid-19 Assessment 12 Sep 2020**

**Form: Symptom Log (1)**

**Generated On: 09 Jun 2021 17:27:05**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User entered '%'	System	25 Jan 2021 23:51:43



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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:05

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered '99.7' F	(b) (4)	25 Jan 2021 23:51:43

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Mild (Mild)'	(b) (4)	25 Jan 2021 23:51:43

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:51:43

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:51:43

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:51:43
	Brandon Illickal (b) (4)	

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Mild (Mild)'	(b) (4)	25 Jan 2021 23:51:43
	Brandon Illickal (b) (4)	

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:51:43
	Brandon Illickal (b) (4)	

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:51:43
	Brandon Illickal (b) (4)	



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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:51:43

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:51:43

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:51:43

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Mild (Mild)'	(b) (4)	25 Jan 2021 23:51:43
	Brandon Illickal (b) (4)	

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:51:43

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**Folder: Covid-19 Assessment 12 Sep 2020**

**Form: Symptom Log (1)**

**Generated On: 09 Jun 2021 17:27:05**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:51:43
	Brandon Illickal (b) (4)	

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:51:43
	Brandon Illickal (b) (4)	

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:51:43



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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:51:43
	Brandon Illickal (b) (4)	

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Day 2 (Day 2)'	(b) (4)	25 Jan 2021 23:55:05
	Brandon Illickal (b) (4)	

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered '12 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Brandon Illickal (b) (4)	25 Jan 2021 23:56:52
User entered '13 Sep 2020'	(b) (4)	
	Brandon Illickal (b) (4)	25 Jan 2021 23:55:05
	(b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered '0'	(b) (4) Brandon Illickal (b) (4)	25 Jan 2021 23:55:05

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered missing code ND - Not Done.	(b) (4)	25 Jan 2021 23:55:05

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**Folder: Covid-19 Assessment 12 Sep 2020**

**Form: Symptom Log (2)**

**Generated On: 09 Jun 2021 17:27:05**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User entered '%'	System	25 Jan 2021 23:55:05

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered missing code ND - Not Done.	(b) (4)	25 Jan 2021 23:55:05
	Brandon Illickal (b) (4)	

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Mild (Mild)'	(b) (4)	25 Jan 2021 23:55:05
	Brandon Illickal (b) (4)	



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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:55:05
	Brandon Illickal (b) (4)	

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:55:05
	Brandon Illickal (b) (4)	

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:55:05
	Brandon Illickal (b) (4)	

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Mild (Mild)'	(b) (4)	25 Jan 2021 23:55:05
	Brandon Illickal (b) (4)	

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:55:05
	Brandon Illickal (b) (4)	

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:55:05
	Brandon Illickal (b) (4)	

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:55:05
	Brandon Illickal (b) (4)	

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:55:05
	Brandon Illickal (b) (4)	



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Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:55:05
	Brandon Illickal (b) (4)	

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Mild (Mild)'	(b) (4)	25 Jan 2021 23:55:05
	Brandon Illickal (b) (4)	

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:55:05

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:55:05
	Brandon Illickal (b) (4)	

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:55:05
	Brandon Illickal (b) (4)	

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Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:55:05
	Brandon Illickal (b) (4)	

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:55:05
	Brandon Illickal (b) (4)	

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Day 3 (Day 3)'	(b) (4)	25 Jan 2021 23:56:36



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Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered '13 Sep 2020'	(b) (4)	25 Jan 2021 23:56:36
	Brandon Illickal (b) (4)	

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**Folder: Covid-19 Assessment 12 Sep 2020**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 17:27:05**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered '0'	(b) (4) Brandon Illickal (b) (4)	25 Jan 2021 23:56:36

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered missing code ND - Not Done.	(b) (4)	25 Jan 2021 23:56:36

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**Folder: Covid-19 Assessment 12 Sep 2020**

**Form: Symptom Log (3)**

**Generated On: 09 Jun 2021 17:27:05**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User entered '%'	System	25 Jan 2021 23:56:36

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered missing code ND - Not Done.	(b) (4)	25 Jan 2021 23:56:36

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Mild (Mild)'	(b) (4)	25 Jan 2021 23:56:36

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:56:36
	Brandon Illickal (b) (4)	

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:56:36



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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:56:36

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Mild (Mild)'	(b) (4)	25 Jan 2021 23:56:36

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:56:36
	Brandon Illickal (b) (4)	

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:56:36
	Brandon Illickal (b) (4)	

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Mild (Mild)'	(b) (4)	25 Jan 2021 23:56:36
	Brandon Illickal (b) (4)	

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:56:36

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:56:36

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Mild (Mild)'	(b) (4)	25 Jan 2021 23:56:36
	Brandon Illickal (b) (4)	



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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:56:36

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:56:36
	Brandon Illickal (b) (4)	

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:56:36
	Brandon Illickal (b) (4)	

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:56:36
	Brandon Illickal (b) (4)	

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:56:36

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Day 4 (Day 4)' reason for change: Data Entry Error	(b) (4) Brandon Illickal (b) (4)	25 Jan 2021 23:58:41
User entered empty.	Brandon Illickal (b) (4)	25 Jan 2021 23:56:52

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Jan 2021 23:58:41
User entered '14 Sep 2020' reason for change: Data Entry Error	System	25 Jan 2021 23:58:41
User opened query 'Data is required. Please complete.' (Site from System).	Brandon Illickal (b) (4)	25 Jan 2021 23:58:41
User entered empty.	System	25 Jan 2021 23:56:52
	Brandon Illickal (b) (4)	25 Jan 2021 23:56:52

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**Folder: Covid-19 Assessment 12 Sep 2020**

**Form: Symptom Log (4)**

**Generated On: 09 Jun 2021 17:27:05**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered '0'	(b) (4) Brandon Illickal (b) (4)	25 Jan 2021 23:56:52



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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered '96' reason for change: Data Entry Error	(b) (4) Brandon Illickal (b) (4)	25 Jan 2021 23:58:41
User entered empty.	(b) (4) Brandon Illickal (b) (4)	25 Jan 2021 23:56:52

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**Folder: Covid-19 Assessment 12 Sep 2020**

**Form: Symptom Log (4)**

**Generated On: 09 Jun 2021 17:27:05**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User entered '%'	System	25 Jan 2021 23:58:41
User entered empty.	System	25 Jan 2021 23:56:52

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered '102.5' F reason for change: Data Entry Error	(b) (4) Brandon Illickal (b) (4)	25 Jan 2021 23:58:41
User entered empty.	Brandon Illickal (b) (4)	25 Jan 2021 23:56:52

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	25 Jan 2021 23:58:41
User entered empty.	Brandon Illickal (b) (4)	25 Jan 2021 23:56:52

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	25 Jan 2021 23:58:41
User entered empty.	Brandon Illickal (b) (4)	25 Jan 2021 23:56:52

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	25 Jan 2021 23:58:41
User entered empty.	Brandon Illickal (b) (4)	25 Jan 2021 23:56:52

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) Brandon Illickal (b) (4)	25 Jan 2021 23:58:41
User entered empty.	Brandon Illickal (b) (4)	25 Jan 2021 23:56:52

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Brandon Illickal (b) (4)	25 Jan 2021 23:58:41
User entered empty.	(b) (4)	
	Brandon Illickal (b) (4)	25 Jan 2021 23:56:52
	(b) (4)	
	(b) (4)	



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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	25 Jan 2021 23:58:41
User entered empty.	Brandon Illickal (b) (4)	25 Jan 2021 23:56:52

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	25 Jan 2021 23:58:41
User entered empty.	Brandon Illickal (b) (4)	25 Jan 2021 23:56:52

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	25 Jan 2021 23:58:41
User entered empty.	Brandon Illickal (b) (4)	25 Jan 2021 23:56:52

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	25 Jan 2021 23:58:41
User entered empty.	Brandon Illickal (b) (4)	25 Jan 2021 23:56:52

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) Brandon Illickal (b) (4)	25 Jan 2021 23:58:41
User entered empty.	Brandon Illickal (b) (4)	25 Jan 2021 23:56:52

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Brandon Illickal (b) (4)	25 Jan 2021 23:58:41
User entered empty.	(b) (4)	
	Brandon Illickal (b) (4)	25 Jan 2021 23:56:52

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	25 Jan 2021 23:58:41
User entered empty.	Brandon Illickal (b) (4)	25 Jan 2021 23:56:52

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	25 Jan 2021 23:58:41
User entered empty.	Brandon Illickal (b) (4)	25 Jan 2021 23:56:52



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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) Brandon Illickal (b) (4)	25 Jan 2021 23:58:41
User entered empty.	Brandon Illickal (b) (4)	25 Jan 2021 23:56:52

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Brandon Illickal (b) (4)	25 Jan 2021 23:58:41
User entered empty.	(b) (4)	
	Brandon Illickal (b) (4)	25 Jan 2021 23:56:52
	(b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) Brandon Illickal (b) (4)	25 Jan 2021 23:58:41
User entered empty.	Brandon Illickal (b) (4)	25 Jan 2021 23:56:52

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Day 5 (Day 5)'	(b) (4)	25 Jan 2021 23:59:31

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered '15 Sep 2020'	(b) (4)	25 Jan 2021 23:59:31
	Brandon Illickal (b) (4)	

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**Folder: Covid-19 Assessment 12 Sep 2020**

**Form: Symptom Log (5)**

**Generated On: 09 Jun 2021 17:27:05**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered '0'	(b) (4) Brandon Illickal (b) (4)	25 Jan 2021 23:59:31

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered missing code ND - Not Done.	(b) (4)	25 Jan 2021 23:59:31

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User entered '%'	System	25 Jan 2021 23:59:31



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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered '100.3' F	(b) (4)	25 Jan 2021 23:59:31

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:59:31
	Brandon Illickal (b) (4)	

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:59:31

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:59:31

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:59:31
	Brandon Illickal (b) (4)	

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Mild (Mild)'	(b) (4)	25 Jan 2021 23:59:31

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:59:31
	Brandon Illickal (b) (4)	

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:59:31
	Brandon Illickal (b) (4)	



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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:59:31
	Brandon Illickal (b) (4)	

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:59:31

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:59:31

**US3392149**

**Folder: Covid-19 Assessment 12 Sep 2020**

**Form: Symptom Log (5)**

**Generated On: 09 Jun 2021 17:27:05**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:59:31
	Brandon Illickal (b) (4)	

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:59:31

**US3392149**

**Folder: Covid-19 Assessment 12 Sep 2020**

**Form: Symptom Log (5)**

**Generated On: 09 Jun 2021 17:27:05**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:59:31
	Brandon Illickal (b) (4)	

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:59:31

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:59:31
	Brandon Illickal (b) (4)	



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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	25 Jan 2021 23:59:31
	Brandon Illickal (b) (4)	

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Day 6 (Day 6)'	(b) (4)	26 Jan 2021 00:02:08
	Brandon Illickal (b) (4)	

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:05

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User closed query 'Please complete eCRF for all Symptom Log. As per CCG: "If a symptom is not assessed on a specific Day, enter 'ND' for the symptom. Do not leave the field blank. If a symptom is reported but the severity has not been provided, select 'Mild' for the symptom from the dropdown list.'" (Site from CRA).	(b) (4) (b) (4), (b) (6)	24 Mar 2021 14:58:08
Query 'Please complete eCRF for all Symptom Log. As per CCG: "If a symptom is not assessed on a specific Day, enter 'ND' for the symptom. Do not leave the field blank. If a symptom is reported but the severity has not been provided, select 'Mild' for the symptom from the dropdown list.'" answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 21:23:34
User opened query 'Please complete eCRF for all Symptom Log. As per CCG: "If a symptom is not assessed on a specific Day, enter 'ND' for the symptom. Do not leave the field blank. If a symptom is reported but the severity has not been provided, select 'Mild' for the symptom from the dropdown list.'" (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 15:08:57
User entered '16 Sep 2020'	Brandon Illickal (b) (4)	26 Jan 2021 00:02:08

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'I'	(b) (4)	26 Jan 2021 00:02:08
	Brandon Illickal (b) (4)	

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered empty.	(b) (4)	26 Jan 2021 00:02:08
	Brandon Illickal (b) (4)	

**US3392149**

**Folder: Covid-19 Assessment 12 Sep 2020**

**Form: Symptom Log (6)**

**Generated On: 09 Jun 2021 17:27:05**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User entered empty.	System	26 Jan 2021 00:02:08

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered empty.	(b) (4)	26 Jan 2021 00:02:08
	Brandon Illickal (b) (4)	

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:23:28
User entered empty.	Brandon Illickal (b) (4)	26 Jan 2021 00:02:08



US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:23:28
User entered empty.	Brandon Illickal (b) (4)	26 Jan 2021 00:02:08

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:23:28
User entered empty.	Brandon Illickal (b) (4)	26 Jan 2021 00:02:08

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:23:28
User entered empty.	Brandon Illickal (b) (4)	26 Jan 2021 00:02:08

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:23:28
User entered empty.	Brandon Illickal (b) (4)	26 Jan 2021 00:02:08

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:23:28
User entered empty.	Brandon Illickal (b) (4)	26 Jan 2021 00:02:08

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:23:28
User entered empty.	Brandon Illickal (b) (4)	26 Jan 2021 00:02:08

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:23:28
User entered empty.	Brandon Illickal (b) (4)	26 Jan 2021 00:02:08

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:23:28
User entered empty.	Brandon Illickal (b) (4)	26 Jan 2021 00:02:08



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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:23:28
User entered empty.	Brandon Illickal (b) (4)	26 Jan 2021 00:02:08

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:23:28
User entered empty.	Brandon Illickal (b) (4)	26 Jan 2021 00:02:08

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:23:28
User entered empty.	Brandon Illickal (b) (4)	26 Jan 2021 00:02:08

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:23:28
User entered empty.	Brandon Illickal (b) (4)	26 Jan 2021 00:02:08

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:23:28
User entered empty.	Brandon Illickal (b) (4)	26 Jan 2021 00:02:08

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:23:28
User entered empty.	Brandon Illickal (b) (4)	26 Jan 2021 00:02:08

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:23:28
User entered empty.	Brandon Illickal (b) (4)	26 Jan 2021 00:02:08

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Day 7 (Day 7)'	(b) (4)	26 Jan 2021 00:02:25
	Brandon Illickal (b) (4)	



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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:05

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User closed query 'Please complete eCRF for all Symptom Log. As per CCG: "If a symptom is not assessed on a specific Day, enter 'ND' for the symptom. Do not leave the field blank. If a symptom is reported but the severity has not been provided, select 'Mild' for the symptom from the dropdown list.'" (Site from CRA).	(b) (4) (b) (4), (b) (6)	24 Mar 2021 14:58:14
Query 'Please complete eCRF for all Symptom Log. As per CCG: "If a symptom is not assessed on a specific Day, enter 'ND' for the symptom. Do not leave the field blank. If a symptom is reported but the severity has not been provided, select 'Mild' for the symptom from the dropdown list.'" answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 21:25:09
User opened query 'Please complete eCRF for all Symptom Log. As per CCG: "If a symptom is not assessed on a specific Day, enter 'ND' for the symptom. Do not leave the field blank. If a symptom is reported but the severity has not been provided, select 'Mild' for the symptom from the dropdown list.'" (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 15:09:14
User entered '17 Sep 2020'	Brandon Illickal (b) (4)	26 Jan 2021 00:02:25

**US3392149**

**Folder: Covid-19 Assessment 12 Sep 2020**

**Form: Symptom Log (7)**

**Generated On: 09 Jun 2021 17:27:05**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'I'	(b) (4) Brandon Illickal (b) (4)	26 Jan 2021 00:02:25

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered empty.	(b) (4)	26 Jan 2021 00:02:25
	Brandon Illickal (b) (4)	

**US3392149**

**Folder: Covid-19 Assessment 12 Sep 2020**

**Form: Symptom Log (7)**

**Generated On: 09 Jun 2021 17:27:05**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User entered empty.	System	26 Jan 2021 00:02:25

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered empty.	(b) (4)	26 Jan 2021 00:02:25
	Brandon Illickal (b) (4)	

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:24:23
User entered empty.	Brandon Illickal (b) (4)	26 Jan 2021 00:02:25

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:24:23
User entered empty.	Brandon Illickal (b) (4)	26 Jan 2021 00:02:25

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:24:23
User entered empty.	Brandon Illickal (b) (4)	26 Jan 2021 00:02:25



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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:24:23
User entered empty.	Brandon Illickal (b) (4)	26 Jan 2021 00:02:25

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:24:23
User entered empty.	Brandon Illickal (b) (4)	26 Jan 2021 00:02:25

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:24:23
User entered empty.	Brandon Illickal (b) (4)	26 Jan 2021 00:02:25

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Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:24:23
User entered empty.	Brandon Illickal (b) (4)	26 Jan 2021 00:02:25

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:24:23
User entered empty.	Brandon Illickal (b) (4)	26 Jan 2021 00:02:25

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:24:23
User entered empty.	Brandon Illickal (b) (4)	26 Jan 2021 00:02:25

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:24:23
User entered empty.	Brandon Illickal (b) (4)	26 Jan 2021 00:02:25

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:24:23
User entered empty.	Brandon Illickal (b) (4)	26 Jan 2021 00:02:25



US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:24:23
User entered empty.	Brandon Illickal (b) (4)	26 Jan 2021 00:02:25

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:24:23
User entered empty.	Brandon Illickal (b) (4)	26 Jan 2021 00:02:25

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:24:23
User entered empty.	Brandon Illickal (b) (4)	26 Jan 2021 00:02:25

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:24:23
User entered empty.	Brandon Illickal (b) (4)	26 Jan 2021 00:02:25

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:24:23
User entered empty.	Brandon Illickal (b) (4)	26 Jan 2021 00:02:25

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Day 8 (Day 8)'	(b) (4)	26 Jan 2021 00:03:30
	Brandon Illickal (b) (4)	

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered '18 Sep 2020'	(b) (4)	26 Jan 2021 00:03:30
	Brandon Illickal (b) (4)	

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered '0'	(b) (4)	26 Jan 2021 00:03:30
	Brandon Illickal (b) (4)	



US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered missing code ND - Not Done.	(b) (4)	26 Jan 2021 00:03:30

**US3392149**

**Folder: Covid-19 Assessment 12 Sep 2020**

**Form: Symptom Log (8)**

**Generated On: 09 Jun 2021 17:27:05**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User entered '%'	System	26 Jan 2021 00:03:30

**US3392149**

**Folder: Covid-19 Assessment 12 Sep 2020**

**Form: Symptom Log (8)**

**Generated On: 09 Jun 2021 17:27:05**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered missing code ND - Not Done.	(b) (4)	26 Jan 2021 00:03:30

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	26 Jan 2021 00:03:30
	Brandon Illickal (b) (4)	

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	26 Jan 2021 00:03:30
	Brandon Illickal (b) (4)	

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	26 Jan 2021 00:03:30
	Brandon Illickal (b) (4)	

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	26 Jan 2021 00:03:30
	Brandon Illickal (b) (4)	

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	26 Jan 2021 00:03:30
	Brandon Illickal (b) (4)	



US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	26 Jan 2021 00:03:30
	Brandon Illickal (b) (4)	

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	26 Jan 2021 00:03:30
	Brandon Illickal (b) (4)	

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	26 Jan 2021 00:03:30
	Brandon Illickal (b) (4)	

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	26 Jan 2021 00:03:30

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	26 Jan 2021 00:03:30
	Brandon Illickal (b) (4)	

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	26 Jan 2021 00:03:30

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	26 Jan 2021 00:03:30

**US3392149**

**Folder: Covid-19 Assessment 12 Sep 2020**

**Form: Symptom Log (8)**

**Generated On: 09 Jun 2021 17:27:05**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	26 Jan 2021 00:03:30
	Brandon Illickal (b) (4)	



US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	26 Jan 2021 00:03:30
	Brandon Illickal (b) (4)	

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	26 Jan 2021 00:03:30
	Brandon Illickal (b) (4)	

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'None (None)'	(b) (4)	26 Jan 2021 00:03:30
	Brandon Illickal (b) (4)	

**US3392149**

**Folder: Covid-19 Assessment 12 Sep 2020**

**Form: COVID Diagnostic Test**

**Generated On: 09 Jun 2021 17:27:05**

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered '12 Sep 2020'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 22:31:22

**US3392149**

**Folder: Covid-19 Assessment 12 Sep 2020**

**Form: COVID Diagnostic Test**

**Generated On: 09 Jun 2021 17:27:05**

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 22:31:22

**US3392149**

**Folder: Covid-19 Assessment 12 Sep 2020**

**Form: COVID Diagnostic Test**

**Generated On: 09 Jun 2021 17:27:05**

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 22:31:22

**US3392149**

**Folder: Covid-19 Assessment 12 Sep 2020**

**Form: COVID Diagnostic Test**

**Generated On: 09 Jun 2021 17:27:05**

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered '12 Sep 2020'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 22:31:22

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:27:05

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 22:31:22



US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:27:05

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 22:31:22

**US3392149**

**Folder: Covid-19 Assessment 12 Sep 2020**

**Form: COVID Diagnostic Test**

**Generated On: 09 Jun 2021 17:27:05**

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 22:31:22

US3392149

Folder: Covid-19 Assessment 12 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:27:05

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 22:31:22

**US3392149**

**Folder: Covid-19 Assessment 12 Sep 2020**

**Form: COVID Diagnostic Test**

**Generated On: 09 Jun 2021 17:27:05**

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 22:31:22

**US3392149**

**Folder: Covid-19 Assessment 12 Sep 2020**

**Form: COVID Diagnostic Test**

**Generated On: 09 Jun 2021 17:27:05**

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:04
User entered '0'	System	04 Jan 2021 22:31:22

US3392149

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:27:05

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 18SEP2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 17:34:17
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 18SEP2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' ' answered with 'collection date updated' (Site from DM).	Brandon Illickal (b) (4)	21 Dec 2020 16:41:27
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 18SEP2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 08:47:35
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	31 Oct 2020 18:20:55

**US3392149**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 17:27:05**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Brandon Illickal (b) (4)	05 Feb 2021 23:35:01
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4), (b) (6)	31 Oct 2020 18:20:55

**US3392149**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 17:27:05**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
	(b) (4)	
User entered '18 Sep 2020' reason for change: Per Query Resolution	Brandon Illickal (b) (4)	21 Dec 2020 16:41:15
User entered empty.	(b) (4), (b) (6)	31 Oct 2020 18:20:55



**US3392149**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 17:27:05**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	31 Oct 2020 18:20:55

**US3392149**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 17:27:05**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	31 Oct 2020 18:20:55

**US3392149**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 17:27:05**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Oct 2020 18:20:55

**US3392149**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 17:27:05**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	31 Oct 2020 18:20:55

**US3392149**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 17:27:05**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	31 Oct 2020 18:20:55

**US3392149**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 17:27:05**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Oct 2020 18:20:55

**US3392149**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 17:27:05**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	31 Oct 2020 18:20:55

**US3392149**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 17:27:05**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	31 Oct 2020 18:20:55



**US3392149**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 17:27:05**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Oct 2020 18:20:55

**US3392149**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 17:27:05**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	31 Oct 2020 18:20:55

**US3392149**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 17:27:05**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	31 Oct 2020 18:20:55

**US3392149**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 17:27:05**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Oct 2020 18:20:55

**US3392149**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 17:27:05**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	31 Oct 2020 18:20:55

**US3392149**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 17:27:05**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	31 Oct 2020 18:20:55

**US3392149**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 17:27:05**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Oct 2020 18:20:55

**US3392149**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 17:27:05**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	31 Oct 2020 18:20:55



**US3392149**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 17:27:05**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	31 Oct 2020 18:20:55

**US3392149**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 17:27:05**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Oct 2020 18:20:55

**US3392149**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:27:05**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:16:27
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Oct 2020 18:15:13

**US3392149**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:16:27
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered '12 Sep 2020'	(b) (4) (b) (4), (b) (6)	31 Oct 2020 18:15:13

**US3392149**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:16:27
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	31 Oct 2020 18:15:13

**US3392149**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:27:05**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:16:27
User entered 'SICKD1'	System	31 Oct 2020 18:15:13

**US3392149**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:27:05**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:16:27
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Oct 2020 18:18:11

US3392149

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:05

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:16:27
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	31 Oct 2020 18:18:51
User entered '12 Sep 2020' reason for change: Data Entry Error	System	31 Oct 2020 18:18:51
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	31 Oct 2020 18:18:11
User entered '30 Sep 2020'	(b) (4), (b) (6)	31 Oct 2020 18:18:11



**US3392149**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:16:27
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered '10:10'	(b) (4) (b) (4), (b) (6)	31 Oct 2020 18:18:11

**US3392149**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:16:27
User entered '12 Sep 2020 10:10'	System	31 Oct 2020 18:18:51
User entered '30 Sep 2020 10:10'	System	31 Oct 2020 18:18:11

**US3392149**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:16:27
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	31 Oct 2020 18:18:11
DataPoint set to visible.	System	31 Oct 2020 18:15:13

**US3392149**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:16:27
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	31 Oct 2020 18:18:11
DataPoint set to visible.	System	31 Oct 2020 18:15:13

**US3392149**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:16:27
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered '99.7' F	(b) (4) (b) (4), (b) (6)	31 Oct 2020 18:18:11

**US3392149**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:27:05**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:16:27
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	31 Oct 2020 18:18:11

**US3392149**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:27:05**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:16:27
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Oct 2020 18:18:11

**US3392149**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:27:05**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:16:27
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered '87'	(b) (4) (b) (4), (b) (6)	31 Oct 2020 18:18:11



**US3392149**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:27:05**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:16:27
User entered 'bpm'	System	31 Oct 2020 18:18:11

**US3392149**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:16:27
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered '16'	(b) (4) (b) (4), (b) (6)	31 Oct 2020 18:18:11

**US3392149**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:27:05**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:16:27
User entered 'breaths/min'	System	31 Oct 2020 18:18:11

**US3392149**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:16:27
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered '170'	(b) (4) (b) (4), (b) (6)	31 Oct 2020 18:18:11

**US3392149**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:27:05**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:16:27
User entered 'mmHg'	System	31 Oct 2020 18:18:11

US3392149

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:16:27
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	02 Nov 2020 19:12:13
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	(b) (4), (b) (6)	31 Oct 2020 18:18:31
User opened query 'Diastolic Blood Pressure reportedSystem is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		31 Oct 2020 18:18:11
User entered '104'	(b) (4), (b) (6)	31 Oct 2020 18:18:11

**US3392149**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:27:05**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:16:27
User entered 'mmHg'	System	31 Oct 2020 18:18:11

**US3392149**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:27:05**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:16:27



**US3392149**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:27:05**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:16:27

**US3392149**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:27:05**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:16:27
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Oct 2020 18:15:28

**US3392149**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:27:05**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:16:27
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered '12 Sep 2020'	(b) (4) (b) (4), (b) (6)	31 Oct 2020 18:15:28

**US3392149**

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 09 Jun 2021 17:27:05**

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:16:27
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Oct 2020 18:19:38

**US3392149**

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 09 Jun 2021 17:27:05**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:16:27
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered '12 Sep 2020'	(b) (4) (b) (4), (b) (6)	31 Oct 2020 18:19:38

**US3392149**

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

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:27:05**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:14:56

**US3392149**

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

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered '1 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:14:56

**US3392149**

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

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:27:05**

[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 09:07:41
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:14:56



**US3392149**

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

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:27:05**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User entered 'UNBLND_DECIDE'	System	01 Feb 2021 21:14:56

**US3392149**

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

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:27:05**

**Date of updated informed consent** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered '1 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:15:18

**US3392149**

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

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:27:05**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:46:06
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:03:00

**US3392149**

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

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:27:05**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:15:18

US3392149

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

Form: Unblinding

Generated On: 09 Jun 2021 17:27:05

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Apr 2021 13:20:01
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 20:46:12
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	08 Apr 2021 20:46:06
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 20:33:57
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:03:00

US3392149

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

Form: Unblinding

Generated On: 09 Jun 2021 17:27:05

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered '1 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:15:18

US3392149

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

Form: Unblinding

Generated On: 09 Jun 2021 17:27:05

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:15:18

**US3392149**

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

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:27:05**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:15:18



**US3392149**

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

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:27:05**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered 'Not Administered (NA)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:15:18

**US3392149**

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

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:27:05**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:15:18

**US3392149**

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

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:27:05**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User entered empty.	System	01 Feb 2021 21:15:18

**US3392149**

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

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:27:05**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User entered 'I'	System	01 Feb 2021 21:15:18

US3392149

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:27:05

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:17:51

**US3392149**

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

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 17:27:05**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:17:51

**US3392149**

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

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 17:27:05**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User entered empty.	System	01 Feb 2021 21:17:51
DataPoint set to visible.	System	01 Feb 2021 21:15:18

US3392149

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:27:05

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:17:51



**US3392149**

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

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 17:27:05**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:17:51

**US3392149**

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

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 17:27:05**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User entered empty.	System	01 Feb 2021 21:17:51
DataPoint set to visible.	System	01 Feb 2021 21:15:18

**US3392149**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:27:05**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	01 Feb 2021 21:17:51

**US3392149**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:27:05**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:17:51

US3392149

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered '1 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:17:51

**US3392149**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered '13:46'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:17:51

**US3392149**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User entered '1 Feb 2021 13:46'	System	01 Feb 2021 21:17:51

US3392149

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered '98.9' F	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:17:51



**US3392149**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:27:05**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:17:51

**US3392149**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:27:05**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:17:51

**US3392149**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:27:05**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered '77'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:17:51

**US3392149**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:27:05**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User entered 'bpm'	System	01 Feb 2021 21:17:51

US3392149

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered '14'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:17:51

**US3392149**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:27:05**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User entered 'breaths/min'	System	01 Feb 2021 21:17:51

US3392149

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered '130'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:17:51

**US3392149**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:27:05**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User entered 'mmHg'	System	01 Feb 2021 21:17:51



**US3392149**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered '76'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:17:51

**US3392149**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:27:05**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User entered 'mmHg'	System	01 Feb 2021 21:17:51

US3392149

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:27:05

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:17:51

**US3392149**

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

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 17:27:05**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:17:51

**US3392149**

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

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 17:27:05**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User entered empty.	System	01 Feb 2021 21:17:51
DataPoint set to visible.	System	01 Feb 2021 21:15:18

**US3392149**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:27:05**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	01 Feb 2021 21:17:51

**US3392149**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:27:05**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:17:51

**US3392149**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:27:05**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered '1 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:17:51



**US3392149**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered '14:53'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:17:51

**US3392149**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User entered '1 Feb 2021 14:53'	System	01 Feb 2021 21:17:51

US3392149

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	01 Feb 2021 21:18:08
Query 'Data is required. Please provide.' answered by System	System	01 Feb 2021 21:18:08
data change (Site from System).		
User entered '99.3' F reason for change: Data Entry Error	(b) (4), (b) (6)	01 Feb 2021 21:18:08
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Feb 2021 21:17:51
User entered empty.	(b) (4), (b) (6)	01 Feb 2021 21:17:51

**US3392149**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:27:05**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:18:08
User entered empty.	(b) (4), (b) (6)	01 Feb 2021 21:17:51

**US3392149**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:27:05**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:17:51

**US3392149**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:27:05**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered '58'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:17:51

**US3392149**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:27:05**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User entered 'bpm'	System	01 Feb 2021 21:17:51

US3392149

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered '14'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:17:51



**US3392149**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:27:05**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User entered 'breaths/min'	System	01 Feb 2021 21:17:51

**US3392149**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered '121'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:17:51

**US3392149**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:27:05**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User entered 'mmHg'	System	01 Feb 2021 21:17:51

**US3392149**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered '71'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:17:51

**US3392149**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:27:05**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User entered 'mmHg'	System	01 Feb 2021 21:17:51

**US3392149**

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

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:27:05**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:18:13

**US3392149**

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

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:27:05**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:18:13

**US3392149**

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

**Form: Exposure**

**Generated On: 09 Jun 2021 17:27:05**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:18:35



**US3392149**

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

**Form: Exposure**

**Generated On: 09 Jun 2021 17:27:05**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:18:35

US3392149

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

Form: Exposure

Generated On: 09 Jun 2021 17:27:05

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 09:07:41
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:18:35

**US3392149**

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

**Form: Exposure**

**Generated On: 09 Jun 2021 17:27:05**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User entered 'mRNA-1273'	System	01 Feb 2021 21:18:35
DataPoint set to visible.	System	01 Feb 2021 21:15:18

US3392149

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

Form: Exposure

Generated On: 09 Jun 2021 17:27:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered '1 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:18:35

**US3392149**

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

**Form: Exposure**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered '14:23'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:18:35

**US3392149**

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

**Form: Exposure**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User entered '1 Feb 2021 14:23'	System	01 Feb 2021 21:18:35

US3392149

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

Form: Exposure

Generated On: 09 Jun 2021 17:27:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:18:35

**US3392149**

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

**Form: Exposure**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User entered 'ONCE'	System	01 Feb 2021 21:18:35



**US3392149**

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

**Form: Exposure**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User entered 'INTRAMUSCULAR'	System	01 Feb 2021 21:18:35

**US3392149**

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

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:27:05**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:15:47

**US3392149**

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

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:27:05**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered '1 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:15:47

**US3392149**

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

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered '13:54'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:15:47

**US3392149**

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

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User entered '1 Feb 2021 13:54'	System	01 Feb 2021 21:15:47

**US3392149**

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

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:27:05**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:15:58

**US3392149**

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

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered '1 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:15:58

**US3392149**

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

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered '13:57'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:15:58



**US3392149**

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

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User entered '1 Feb 2021 13:57'	System	01 Feb 2021 21:15:58

**US3392149**

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

**Form: Continuing**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:16:02

**US3392149**

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

**Form: Continuing**

**Generated On: 09 Jun 2021 17:27:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:41
User entered 'I'	System	01 Feb 2021 21:16:02

**US3392149**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:27:05**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:23:04
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	08 Feb 2021 23:17:05

**US3392149**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:23:04
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered '08 Feb 2021'	Brenda Lawson (b) (4)	08 Feb 2021 23:17:05

**US3392149**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:27:05**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:23:04
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered 'Contact Made (CONTACT MADE)'	Brenda Lawson (b) (4)	08 Feb 2021 23:17:05

**US3392149**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:27:05**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:23:04
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered empty.	Brenda Lawson (b) (4)	08 Feb 2021 23:17:05

**US3392149**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:23:04
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	08 Feb 2021 23:17:13



**US3392149**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:27:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:23:04
User entered 'I'	System	08 Feb 2021 23:17:13

**US3392149**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:27:05**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:23:04
User entered 'I'	System	08 Feb 2021 23:17:13
DataPoint set to visible.	System	08 Feb 2021 23:17:13

**US3392149**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 09 Jun 2021 17:27:05**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:25:19
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:41:44
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	28 Sep 2020 18:40:36

**US3392149**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:27:05**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:42:20
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:13:51
User entered	System	29 Sep 2020 14:13:47
'USA-US119-2020-mRNA-1273-P301000003'		
User entered 'New'	(b) (4), (b) (6)	29 Sep 2020 14:13:47

US3392149

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:05

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:20
User signature succeeded.	Michael Cotugno (b) (4)	28 Sep 2020 21:31:09
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Hepatitis viral infections, PT: Hepatitis A, LLT: Hepatitis A - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 19:01:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 19:01:38
Data point term sent to Coder	System	28 Sep 2020 19:00:38
User entered 'Hepatitis A'	Brandon Illickal (b) (4)	28 Sep 2020 18:59:44

**US3392149**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:27:05**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:20
User signature succeeded.	Michael Cotugno (b) (4)	28 Sep 2020 21:31:09
User entered 'Yes (Y)'	(b) (4)	28 Sep 2020 18:59:44
	Brandon Illickal (b) (4)	

**US3392149**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:27:05**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:20
User signature succeeded.	Michael Cotugno (b) (4)	28 Sep 2020 21:31:09
User entered 'No (N)'	(b) (4)	28 Sep 2020 18:59:44
	Brandon Illickal (b) (4)	

**US3392149**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:27:05**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:20
User signature succeeded.	Michael Cotugno (b) (4)	28 Sep 2020 21:31:09
User entered 'No (N)'	(b) (4) Brandon Illickal (b) (4)	28 Sep 2020 18:59:44



**US3392149**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:20
User signature succeeded.	Michael Cotugno (b) (4)	28 Sep 2020 21:31:09
User entered '24 Sep 2020'	(b) (4)	28 Sep 2020 18:59:44
	Brandon Illickal (b) (4)	

US3392149

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:42:20
User closed query 'Per CDM re-query: Thank you for your answer. Please consider removing time because AE was not 24 hours after dosing. Thank you!' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 05:53:18
Query 'Per CDM re-query: Thank you for your answer. Please consider removing time because AE was not 24 hours after dosing. Thank you!' answered with 'updated' (Site from DM).	Brandon Illickal (b) (4)	02 Oct 2020 16:41:32
Signature has been broken.	Brandon Illickal (b) (4)	02 Oct 2020 16:41:06
User entered empty; reason for change Data Entry Error	Brandon Illickal (b) (4)	02 Oct 2020 16:41:06
User opened query 'Per CDM re-query: Thank you for your answer. Please consider removing time because AE was not 24 hours after dosing. Thank you!' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 08:26:20
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	(b) (4), (b) (6)	02 Oct 2020 08:26:16
User signature succeeded.	Michael Cotugno (b) (4)	28 Sep 2020 21:31:09
User entered '20:00' reason for change: Data Entry Error	Michael Cotugno (b) (4)	28 Sep 2020 21:30:48
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	28 Sep 2020 20:38:17
User entered '12:00' reason for change: Data Entry Error	Brandon Illickal (b) (4)	28 Sep 2020 20:38:17
Query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' answered with 'time unknown' (Site from System).	Brandon Illickal (b) (4)	28 Sep 2020 18:59:55
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	28 Sep 2020 18:59:44
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	28 Sep 2020 18:59:44

**US3392149**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
User entered 'un:un' (non-conformant).	Brandon Illickal (b) (4)	28 Sep 2020 18:59:44

**US3392149**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:27:05**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 16:41:06
User entered '24 Sep 2020 20:00'	System	28 Sep 2020 21:30:48
User entered '24 Sep 2020 12:00'	System	28 Sep 2020 20:38:17
User entered '24 Sep 2020 UN:UN' (non-conformant).	System	28 Sep 2020 18:59:44

US3392149

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:05

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:42:20
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	06 Nov 2020 18:55:44
Signature has been broken.	Brandon Illickal (b) (4)	06 Nov 2020 18:55:44
User entered 'No (N)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	06 Nov 2020 18:55:44
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	06 Nov 2020 18:55:23
User signature succeeded.	Michael Cotugno (b) (4)	28 Sep 2020 21:31:09
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Michael Cotugno (b) (4)	28 Sep 2020 21:30:48
	(b) (4)	
User entered 'No (N)'	Brandon Illickal (b) (4)	28 Sep 2020 18:59:44

US3392149

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:05

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:42:20
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 15:49:55
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4), (b) (6)	09 Nov 2020 14:46:40
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered with 'recovered/resolved' (Site from System).	Brandon Illickal (b) (4)	06 Nov 2020 18:56:26
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'end date is 25SEP2020' (Site from Safety).	Brandon Illickal (b) (4)	06 Nov 2020 18:56:16
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	06 Nov 2020 18:55:23
Signature has been broken.	Brandon Illickal (b) (4)	06 Nov 2020 18:55:23
User entered '25 Sep 2020' reason for change: New Information	Brandon Illickal (b) (4)	06 Nov 2020 18:55:23
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 11:59:29
User signature succeeded.	Michael Cotugno (b) (4)	28 Sep 2020 21:31:09
User entered empty; reason for change Data Entry Error	Michael Cotugno (b) (4)	28 Sep 2020 21:30:48
User entered '25 Sep 2020'	Brandon Illickal (b) (4)	28 Sep 2020 18:59:44

US3392149

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:05

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:24
Signature has been broken.	(b) (4)	
	Brandon Illickal (b) (4)	09 Mar 2021 17:57:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:20
	(b) (4)	
User signature succeeded.	Michael Cotugno (b) (4)	28 Sep 2020 21:31:09
	(b) (4)	
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	28 Sep 2020 21:30:48
User entered empty; reason for change Data Entry Error	Michael Cotugno (b) (4)	28 Sep 2020 21:30:48
	(b) (4)	
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	28 Sep 2020 20:38:17
User entered '12:00' reason for change: Data Entry Error	Brandon Illickal (b) (4)	28 Sep 2020 20:38:17
	(b) (4)	
Query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' answered with 'time unknown' (Site from System).	Brandon Illickal (b) (4)	28 Sep 2020 19:00:14
	(b) (4)	
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	28 Sep 2020 18:59:44
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	28 Sep 2020 18:59:44
User entered 'un:un' (non-conformant).	Brandon Illickal (b) (4)	28 Sep 2020 18:59:44
	(b) (4)	
	(b) (4)	

**US3392149**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:27:05**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 21:30:48
User entered '25 Sep 2020 12:00'	System	28 Sep 2020 20:38:17
User entered '25 Sep 2020 UN:UN' (non-conformant).	System	28 Sep 2020 18:59:44



**US3392149**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:27:05**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:20
User signature succeeded.	Michael Cotugno (b) (4)	28 Sep 2020 21:31:09
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) Brandon Illickal (b) (4)	28 Sep 2020 18:59:44

**US3392149**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:27:05**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:20
User signature succeeded.	Michael Cotugno (b) (4)	28 Sep 2020 21:31:09
User entered 'Yes (Y)'	(b) (4)	28 Sep 2020 18:59:44
	Brandon Illickal (b) (4)	

**US3392149**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:27:05**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:20
User signature succeeded.	Michael Cotugno (b) (4)	28 Sep 2020 21:31:09
User entered '0'	(b) (4) Brandon Illickal (b) (4)	28 Sep 2020 18:59:44

**US3392149**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:27:05**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:20
User signature succeeded.	Michael Cotugno (b) (4)	28 Sep 2020 21:31:09
User entered '0'	(b) (4) Brandon Illickal (b) (4)	28 Sep 2020 18:59:44

**US3392149**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:27:05**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:20
User signature succeeded.	Michael Cotugno (b) (4)	28 Sep 2020 21:31:09
User entered 'I'	(b) (4) Brandon Illickal (b) (4)	28 Sep 2020 18:59:44

US3392149

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:05

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:24
	(b) (4)	
Signature has been broken.	Brandon Illickal (b) (4)	27 Apr 2021 18:48:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:20
User signature succeeded.	Michael Cotugno (b) (4)	28 Sep 2020 21:31:09
	(b) (4)	
User entered '24 Sep 2020'	Brandon Illickal (b) (4)	28 Sep 2020 18:59:44

US3392149

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:05

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:20
User closed query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 15:50:12
Query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' answered with 'updated' (Site from Safety).	Brandon Illickal (b) (4)	06 Nov 2020 18:57:02
User opened query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 12:02:08
User signature succeeded.	Michael Cotugno (b) (4)	28 Sep 2020 21:31:09
User entered '25 Sep 2020'	(b) (4)	
	Brandon Illickal (b) (4)	28 Sep 2020 18:59:44

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:27:05**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:20
User signature succeeded.	Michael Cotugno (b) (4)	28 Sep 2020 21:31:09
User entered 'No (N)'	(b) (4)	28 Sep 2020 18:59:44
	Brandon Illickal (b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:27:05**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:20
User signature succeeded.	Michael Cotugno (b) (4)	28 Sep 2020 21:31:09
User entered empty.	(b) (4)	28 Sep 2020 18:59:44
	Brandon Illickal (b) (4)	

**US3392149**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:27:05**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:20
User signature succeeded.	Michael Cotugno (b) (4)	28 Sep 2020 21:31:09
User entered '0'	(b) (4) Brandon Illickal (b) (4)	28 Sep 2020 18:59:44

**US3392149**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:27:05**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:20
User signature succeeded.	Michael Cotugno (b) (4)	28 Sep 2020 21:31:09
User entered '0'	(b) (4) Brandon Illickal (b) (4)	28 Sep 2020 18:59:44

**US3392149**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:27:05**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:20
User signature succeeded.	Michael Cotugno (b) (4)	28 Sep 2020 21:31:09
User entered '0'	(b) (4)	28 Sep 2020 18:59:44
	Brandon Illickal (b) (4)	

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Folder: Adverse Events

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:20
User signature succeeded.	Michael Cotugno (b) (4)	28 Sep 2020 21:31:09
User entered 'Not Related (NOT RELATED)'	(b) (4) Brandon Illickal (b) (4)	28 Sep 2020 18:59:44

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:27:05**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:20
User signature succeeded.	Michael Cotugno (b) (4)	28 Sep 2020 21:31:09
User entered 'Not Related (NOT RELATED)'	(b) (4) Brandon Illickal (b) (4)	28 Sep 2020 18:59:44

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Folder: Adverse Events

Form: Adverse Events (1)

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:42:20
User closed query ' Per MM, please confirm "action taken with IP". If the event occurred around the time scheduled for dosing, the participant may be injected at a later date, as per protocol 7.2 ' (Site from DM). Query ' Per MM, please confirm "action taken with IP". If the event occurred around the time scheduled for dosing, the participant may be injected at a later date, as per protocol 7.2 ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 14:47:06
Signature has been broken.	Brandon Illickal (b) (4)	06 Nov 2020 19:19:33
	Brandon Illickal (b) (4)	06 Nov 2020 18:58:26
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	06 Nov 2020 18:58:26
User opened query ' Per MM, please confirm "action taken with IP". If the event occurred around the time scheduled for dosing, the participant may be injected at a later date, as per protocol 7.2 ' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	30 Oct 2020 12:47:03
	Michael Cotugno (b) (4)	28 Sep 2020 21:31:09
	(b) (4)	
User entered 'None (NONE)'	Brandon Illickal (b) (4)	28 Sep 2020 18:59:44

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:05

None

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:24
DataPoint Un-verified.	(b) (4)	
	Brandon Illickal (b) (4)	09 Mar 2021 18:02:06
User entered '0' reason for change: New Information	Brandon Illickal (b) (4)	09 Mar 2021 18:02:06
User closed query 'Per CDM Re Query: Response noted. Please confirm and ensure all Concomitant Procedures are recorded. Thank you' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 13:55:40
Query 'Per CDM Re Query: Response noted. Please confirm and ensure all Concomitant Procedures are recorded. Thank you' answered with 'MEDICAL RECORDS RECEIVED BY SITE DO NOT INDICATE MEDICATION ADMINISTERED TO SUBJECT. MEDICAL RECORDS DO SHOW LAB & IMAGING PROCEDURES.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 16:38:37
User opened query 'Per CDM Re Query: Response noted. Please confirm and ensure all Concomitant Procedures are recorded. Thank you' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 14:42:18
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected as the subject was hospitalized for this AE. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment. ' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 14:42:18
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected as the subject was hospitalized for this AE. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment. ' answered with 'MEDICAL RECORDS RECEIVED BY SITE DO NOT INDICATE MEDICATION ADMINISTERED TO SUBJECT. MEDICAL RECORDS DO SHOW LAB & IMAGING PROCEDURES.' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 16:11:03



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None

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected as the subject was hospitalized for this AE. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 14:02:08
User closed query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 07:27:26
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:20
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	10 Nov 2020 17:23:04
User entered '1' reason for change: Data Entry Error	Brandon Illickal (b) (4)	10 Nov 2020 17:23:04
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	10 Nov 2020 17:22:49
Query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' answered with 'waiting for hospital records to confirm medication' (Site from DM).	Brandon Illickal (b) (4)	10 Nov 2020 17:22:34
Signature has been broken.	Brandon Illickal (b) (4)	06 Nov 2020 19:19:59
User entered '0' reason for change: Data Entry Error	Brandon Illickal (b) (4)	06 Nov 2020 19:19:59
User opened query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 07:51:26
User signature succeeded.	Michael Cotugno (b) (4)	28 Sep 2020 21:31:09

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[None](#)

Audit	User	Time (GMT)
User entered '1'	Brandon Illickal (b) (4)	28 Sep 2020 18:59:44

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:24
	(b) (4)	
DataPoint Un-verified.	Brandon Illickal (b) (4)	09 Mar 2021 18:02:06
User entered '1' reason for change: New Information	Brandon Illickal (b) (4)	09 Mar 2021 18:02:06
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:20
User entered '0' reason for change: Data Entry Error	Brandon Illickal (b) (4)	10 Nov 2020 17:22:49
Signature has been broken.	Brandon Illickal (b) (4)	06 Nov 2020 19:19:59
User entered '1' reason for change: Data Entry Error	Brandon Illickal (b) (4)	06 Nov 2020 19:19:59
User signature succeeded.	Michael Cotugno (b) (4)	28 Sep 2020 21:31:09
	(b) (4)	
User entered '0'	Brandon Illickal (b) (4)	28 Sep 2020 18:59:44

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:24
	(b) (4)	
Signature has been broken.	Brandon Illickal (b) (4)	09 Mar 2021 17:57:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:20
User signature succeeded.	Michael Cotugno (b) (4)	28 Sep 2020 21:31:09
	(b) (4)	
User entered '0'	Brandon Illickal (b) (4)	28 Sep 2020 18:59:44

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:05

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:42:20
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 15:50:24
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	Brandon Illickal (b) (4)	06 Nov 2020 19:47:17
Signature has been broken.	Brandon Illickal (b) (4)	06 Nov 2020 18:56:50
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Brandon Illickal (b) (4)	06 Nov 2020 18:56:50
New Information	(b) (4), (b) (6)	08 Oct 2020 11:59:47
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	Michael Cotugno (b) (4)	28 Sep 2020 21:31:09
User signature succeeded.	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Michael Cotugno (b) (4)	28 Sep 2020 21:30:48
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Brandon Illickal (b) (4)	28 Sep 2020 18:59:44

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:20
User signature succeeded.	Michael Cotugno (b) (4)	28 Sep 2020 21:31:09
User entered empty.	(b) (4)	28 Sep 2020 18:59:44
	Brandon Illickal (b) (4)	

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:24
User closed query 'Per DM CLR: Narrative = CHEMISTRITY PANEL, AST (<39 UNITS/L) 156 H @16:55 ON 24/SEP/2020 AND 128H @02:45 ON 25/SEP/2020.. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:31:49
User closed query 'Per DM CLR: Narrative = TOTAL BILI : ~ 12. However, this is not recorded in the ConProc eCRF (e.g., Blood work). Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 14:31:29
Query 'Per DM CLR: Narrative = CHEMISTRITY PANEL, AST (<39 UNITS/L) 156 H @16:55 ON 24/SEP/2020 AND 128H @02:45 ON 25/SEP/2020.. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Concomitant procedures have been updated.' (Site from DM).	Brandon Illickal (b) (4)	13 Apr 2021 20:14:36
Query 'Per DM CLR: Narrative = TOTAL BILI : ~ 12. However, this is not recorded in the ConProc eCRF (e.g., Blood work). Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Concomitant procedures have been updated.' (Site from DM).	Brandon Illickal (b) (4)	13 Apr 2021 20:14:16
User entered 'SUBJECT SEEN IN ER ON 24SEP2020 NAUSEA WITHOUT EMESIS. TX'D WITH ANTI-EMETICS. JAUNDICE NO ED ON EXAM ( TOTAL BILI : ~8.5 ) PER PATIENT. ADMITTED FOR OBSERVATION. DISCHARGE DX : HEPATITIS A. CHEMISTRITY PANEL, AST (<39 UNITS/L) 156 H @16:55 ON 24/SEP/2020 AND 128H @02:45 ON 25/SEP/2020.' reason for change: Per Query Resolution	Brandon Illickal (b) (4)	13 Apr 2021 20:12:42

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Narrative = CHEMISTRITY PANEL, AST (<39 UNITS/L) 156 H @16:55 ON 24/SEP/2020 AND 128H @02:45 ON 25/SEP/2020.. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 10:37:37
User opened query 'Per DM CLR: Narrative = TOTAL BILI : ~ 12. However, this is not recorded in the ConProc eCRF (e.g., Blood work). Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 10:37:31
User closed query 'Per DM CLR: SAE Narrative = SERIAL LABS. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 14:31:46
User closed query 'Per DM CLR: SAE Narrative = IV FLUIDS. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 14:31:41
Query 'Per DM CLR: SAE Narrative = SERIAL LABS. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'updated' (Site from DM).	Brandon Illickal (b) (4)	10 Mar 2021 00:14:34
Query 'Per DM CLR: SAE Narrative = IV FLUIDS. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'IV fluids was not listed on subject's discharge summary' (Site from DM).	Brandon Illickal (b) (4)	10 Mar 2021 00:13:09
User entered 'SUBJECT SEEN IN ER ON 24SEP2020 NAUSEA WITHOUT EMESIS. TX'D WITH ANTI-EMETICS. JAUNDICE NOTED ON EXAM ( TOTAL BILI : ~ 12) PER PATIENT. ADMITTED FOR OBSERVATION. DISCHARGE DX : HEPATITIS A. CHEMISTRITY PANEL, AST (<39 UNITS/L) 156 H @16:55 ON 24/SEP/2020 AND 128H @02:45 ON 25/SEP/2020.' reason for change: Per Query Resolution	Brandon Illickal (b) (4)	09 Mar 2021 18:01:51

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EAB) (1725)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT SEEN IN ER ON 24SEP2020 NAUSEA WITHOUT EMESIS. TX'D WITH ANTI-EMETICS. JAUNDICE NOTED ON EXAM ( TOTAL BILI : ~ 12) PER PATIENT. ADMITTED FOR OBSERVATION / SERIAL LABS X 1 NIGHT; DISCHARGE DX : HEPATITIS A. CHEMISTRTRY PANEL, AST (&lt;39 UNITS/L) 156 H @ 16:55 ON 24/SEP/2020 AND 128H @02:45 ON 25/SEP/2020.' reason for change: Per Query Resolution	Brandon Illickal (b) (4)	09 Mar 2021 17:58:46
User opened query 'Per DM CLR: SAE Narrative = SERIAL LABS. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	07 Feb 2021 12:01:56
User opened query 'Per DM CLR: SAE Narrative = IV FLUIDS. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	07 Feb 2021 12:01:49
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 17:44:26
User closed query 'PV Query: Please leave query unanswered until records are available. 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.' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 17:44:24
User closed query 'PV Query: Please provide any additional 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). Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 17:44:23
User closed query 'Per CDM requery: Response Noted. Please leave query open until information is available.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 15:11:41

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[Narrative](#)

Audit	User	Time (GMT)
Query 'Per CDM requery: Response Noted. Please leave query open until information is available.' answered with 'PLEASE RE-QUERY IF ANY CLARIFICATION IS NEEDED' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 16:12:35
Query 'PV Query: Please provide any additional 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). Please leave query open until information is available. ' answered with 'MEDICAL RECORDS RECEIVED BY SITE DO NOT INDICATE MEDICATION ADMINISTERED TO SUBJECT. MEDICAL RECORDS DO SHOW LAB & IMAGING PROCEDURES.' (Site from Safety).	(b) (4), (b) (6)	06 Jan 2021 16:11:42
Query 'PV Query: Please leave query unanswered until records are available. 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.' answered with 'HAS MODERNA SAFETY RECEIVED REDACTED MEDICAL RECORDS?' (Site from Safety).	(b) (4), (b) (6)	06 Jan 2021 16:11:33
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Please leave query open until information is available. ' answered with 'PROVIDED. DATA UPDATED.' (Site from Safety).	(b) (4), (b) (6)	06 Jan 2021 16:11:14
DataPoint Un-verified.	(b) (4), (b) (6)	06 Jan 2021 16:08:49
Signature has been broken.	(b) (4), (b) (6)	06 Jan 2021 16:08:49

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Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT SEEN IN ER ON 24SEP2020 C/O FATIGUE, NAUSEA WITHOUT EMESIS. TX'D WITH ANTI-EMETICS, IV FLUIDS. JAUNDICE NOTED ON EXAM ( TOTAL BILI : ~ 12) PER PATIENT. ADMITTED FOR OBSERVATION / IVF/ SERIAL LABS X 1 NIGHT; DISCHARGE DX : HEPATITIS A. CHEMISTRITY PANEL, AST (&lt;39 UNITS/L) 156 H @16:55 ON 24/SEP/2020 AND 128H @02:45 ON 25/SEP/2020.' reason for change: Per Query Resolution	(b) (4), (b) (6)	06 Jan 2021 16:08:49
User opened query 'Per CDM requery: Response Noted. Please leave query open until information is available.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 05:56:02
User closed query 'Per CDM Re-query: Response noted, please leave this query open update when data becomes available or comment accordingly. ' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 05:56:02
User opened query 'PV Query: Please provide any additional 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). Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 14:52:40
User closed query 'PV Query: Please provide any additional 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).' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 14:52:40
User opened query 'PV Query: Please leave query unanswered until records are available. 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.' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 14:52:11

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[Narrative](#)

Audit	User	Time (GMT)
User closed 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. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 14:52:11
User closed query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 14:50:47
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 14:50:43
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 14:50:43
Query 'Per CDM Re-query: Response noted, please leave this query open update when data becomes available or comment accordingly.' answered with 'hospital records have been requested. Data will be entered when records are received.' (Site from DM).	Brandon Illickal (b) (4)	25 Nov 2020 17:55:43
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. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'hospital records have been requested. Data will be entered when records are received.' (Site from Safety).	Brandon Illickal (b) (4)	25 Nov 2020 17:55:37

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:05

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any additional 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).' answered with 'hospital records have been requested. Data will be entered when records are received.' (Site from Safety).	Brandon Illickal (b) (4)	25 Nov 2020 17:55:35
Query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' answered with 'subject was hospitalized overnight' (Site from Safety).	Brandon Illickal (b) (4)	25 Nov 2020 17:55:29
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'hospital records have been requested. Data will be entered when records are received.' (Site from Safety).	Brandon Illickal (b) (4)	25 Nov 2020 17:54:54
User opened query 'Per CDM Re-query: Response noted, please leave this query open update when data becomes available or comment accordingly.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 17:48:28
User closed query 'Per DM CLR: SAE Narrative indicates that the subject was treated with anti emetics and iv fluids. However, there are no corresponding ConMed record that match this medications. Please update to record the corresponding ConMeds as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 17:48:28
User closed query 'Per DM CLR: SAE Narrative indicates subject had Nausea and Fatigue. However, there is no corresponding AE record that match these conditions. Please update to record the corresponding AE as applicable. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 14:41:53

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:05

[Narrative](#)

Audit	User	Time (GMT)
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. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 20:50:01
User opened query 'PV Query: Please provide any additional 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).' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 20:49:32
User opened query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 20:49:12
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 20:48:51
User closed 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. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 12:59:56
User closed query 'PV Query: Please provide any additional 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).' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 12:59:53
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 12:59:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:05

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 12:59:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:20
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. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'awaiting all hospital records. Once they are received data will be submitted.' (Site from Safety).	Brandon Illickal (b) (4)	10 Nov 2020 17:27:03
Query 'Per DM CLR: SAE Narrative indicates that the subject was treated with anti emetics and iv fluids. However, there are no corresponding ConMed record that match this medications. Please update to record the corresponding ConMeds as appropriate. Otherwise, clarify.' answered with 'awaiting all hospital records. Once they are received data will be submitted.' (Site from DM).	Brandon Illickal (b) (4)	10 Nov 2020 17:26:59
Query 'Per DM CLR: SAE Narrative indicates subject had Nausea and Fatigue. However, there is no corresponding AE record that match these conditions. Please update to record the corresponding AE as applicable. Otherwise, clarify.' answered with 'AE updated' (Site from DM).	Brandon Illickal (b) (4)	10 Nov 2020 17:26:52
Query 'PV Query: Please provide any additional 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).' answered with 'awaiting all hospital records. Once they are received data will be submitted.' (Site from Safety).	Brandon Illickal (b) (4)	10 Nov 2020 17:24:14
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'awaiting all hospital records. Once they are received data will be submitted.' (Site from Safety).	Brandon Illickal (b) (4)	10 Nov 2020 17:24:11

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' answered with 'Subject tested negative for COVID-19' (Site from Safety).	Brandon Illickal (b) (4)	10 Nov 2020 17:23:26
User opened query 'Per DM CLR: SAE Narrative indicates that the subject was treated with anti emetics and iv fluids. However, there are no corresponding ConMed record that match this medications. Please update to record the corresponding ConMeds as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 07:52:23
User opened query 'Per DM CLR: SAE Narrative indicates subject had Nausea and Fatigue. However, there is no corresponding AE record that match these conditions. Please update to record the corresponding AE as applicable. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 07:52:05
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. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 12:02:40
User opened query 'PV Query: Please provide any additional 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).' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 12:02:29
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 11:59:11
User opened query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 11:59:03
User signature succeeded.	Michael Cotugno (b) (4) (b) (4)	28 Sep 2020 21:31:09



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Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject seen in ER on 24Sep2020 c/o fatigue, nausea without emesis. Tx'd with anti-emetics, IV fluids. Jaundice noted on exam ( Total Bili : ~ 12) per patient. Admitted for OBSERVATION / IVF/ Serial labs x 1 night; Discharge Dx : HEPATITIS A.' reason for change: Per Query Resolution	Michael Cotugno (b) (4)	28 Sep 2020 21:30:48
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	28 Sep 2020 19:01:52
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	28 Sep 2020 19:01:52
User entered 'subject was admitted to hospital overnight. subject was jaundice confirmed by elevated bilirubin. subject was diagnosed with Hepatitis A via lab results. currently waiting for medical records.' reason for change: Per Query Resolution	Brandon Illickal (b) (4)	28 Sep 2020 19:01:52
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	28 Sep 2020 18:59:44
User entered empty.	Brandon Illickal (b) (4)	28 Sep 2020 18:59:44

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:27:05**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	28 Sep 2020 18:59:44

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:27:05**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	28 Sep 2020 18:59:44

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:27:05**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	28 Sep 2020 18:59:44

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:05

[AEID](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Brandon Illickal (b) (4)	27 Apr 2021 18:45:36
DataPoint inactivated with code reason code Data not required.	Brandon Illickal (b) (4)	09 Mar 2021 17:57:09

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Folder: Adverse Events

Form: Adverse Events (2)

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[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:24
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hyperfunction disorders, PT: Hyperthyroidism, LLT: Hyperthyroidism - version MedDRA\\23.0.	Coder Import (b) (4)	27 Apr 2021 19:57:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Apr 2021 19:57:44
Data point term sent to Coder	System	27 Apr 2021 18:46:57
DataPoint Un-verified.	Brandon Illickal (b) (4)	27 Apr 2021 18:46:28
Coding entries removed.	Brandon Illickal (b) (4)	27 Apr 2021 18:46:28
User entered 'hyperthyroidism' reason for change: Data Entry Error	Brandon Illickal (b) (4)	27 Apr 2021 18:46:28
Data point term sent to Coder	System	27 Apr 2021 18:45:55
DataPoint activated with code reason code Data required.	Brandon Illickal (b) (4)	27 Apr 2021 18:45:36
Data point term sent to Coder	System	09 Mar 2021 17:57:20
DataPoint inactivated with code reason code Data not required.	Brandon Illickal (b) (4)	09 Mar 2021 17:57:09
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:20
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 17:29:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 17:29:38
Data point term sent to Coder	System	10 Nov 2020 17:28:57
User entered 'nausea'	Brandon Illickal (b) (4)	10 Nov 2020 17:28:15

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:24
DataPoint Un-verified.	(b) (4)	
	Brandon Illickal (b) (4)	27 Apr 2021 18:48:27
User entered 'Yes (Y)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	27 Apr 2021 18:48:27
DataPoint activated with code reason code Data required.	Brandon Illickal (b) (4)	27 Apr 2021 18:45:36
DataPoint inactivated with code reason code Data not required.	Brandon Illickal (b) (4)	09 Mar 2021 17:57:09
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:20
User entered 'No (N)'	Brandon Illickal (b) (4)	10 Nov 2020 17:28:15

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:27:05**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:24
DataPoint activated with code reason code Data required.	(b) (4) Brandon Illickal (b) (4)	27 Apr 2021 18:45:36
DataPoint inactivated with code reason code Data not required.	Brandon Illickal (b) (4)	09 Mar 2021 17:57:09
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:20
User entered 'No (N)'	Brandon Illickal (b) (4)	10 Nov 2020 17:28:15



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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:24
DataPoint activated with code reason code Data required.	(b) (4) Brandon Illickal (b) (4)	27 Apr 2021 18:45:36
DataPoint inactivated with code reason code Data not required.	(b) (4) Brandon Illickal (b) (4)	09 Mar 2021 17:57:09
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:20
User entered 'No (N)'	Brandon Illickal (b) (4)	10 Nov 2020 17:28:15

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Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:24
DataPoint Un-verified.	(b) (4)	
	Brandon Illickal (b) (4)	27 Apr 2021 18:46:28
User entered '16 Apr 2021' reason for change: Data Entry Error	Brandon Illickal (b) (4)	27 Apr 2021 18:46:28
DataPoint activated with code reason code Data required.	Brandon Illickal (b) (4)	27 Apr 2021 18:45:36
DataPoint inactivated with code reason code Data not required.	Brandon Illickal (b) (4)	09 Mar 2021 17:57:09
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:20
User entered '24 Sep 2020'	Brandon Illickal (b) (4)	10 Nov 2020 17:28:15

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:24
DataPoint activated with code reason code Data required.	(b) (4) Brandon Illickal (b) (4)	27 Apr 2021 18:45:36
DataPoint inactivated with code reason code Data not required.	Brandon Illickal (b) (4)	09 Mar 2021 17:57:09
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:20
User entered empty.	Brandon Illickal (b) (4)	10 Nov 2020 17:28:15

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Form: Adverse Events (2)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Brandon Illickal (b) (4)	27 Apr 2021 18:45:36
DataPoint inactivated with code reason code Data not required.	Brandon Illickal (b) (4)	09 Mar 2021 17:57:09
User entered empty.	System	10 Nov 2020 17:28:15

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Folder: Adverse Events

Form: Adverse Events (2)

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[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:24
DataPoint Un-verified.	(b) (4)	
	Brandon Illickal (b) (4)	27 Apr 2021 18:46:28
User entered 'Yes (Y)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	27 Apr 2021 18:46:28
DataPoint activated with code reason code Data required.	Brandon Illickal (b) (4)	27 Apr 2021 18:45:36
DataPoint inactivated with code reason code Data not required.	Brandon Illickal (b) (4)	09 Mar 2021 17:57:09
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:20
User entered 'No (N)'	Brandon Illickal (b) (4)	10 Nov 2020 17:28:15

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:24
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	(b) (4)	27 Apr 2021 18:46:50
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	27 Apr 2021 18:46:50
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	27 Apr 2021 18:46:28
DataPoint Un-verified.	Brandon Illickal (b) (4)	27 Apr 2021 18:46:28
User entered empty; reason for change Data Entry Error	Brandon Illickal (b) (4)	27 Apr 2021 18:46:28
DataPoint activated with code reason code Data required.	Brandon Illickal (b) (4)	27 Apr 2021 18:45:36
DataPoint inactivated with code reason code Data not required.	Brandon Illickal (b) (4)	09 Mar 2021 17:57:09
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:20
User entered '25 Sep 2020'	Brandon Illickal (b) (4)	10 Nov 2020 17:28:15

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:24
DataPoint activated with code reason code Data required.	(b) (4) Brandon Illickal (b) (4)	27 Apr 2021 18:45:36
DataPoint inactivated with code reason code Data not required.	(b) (4) Brandon Illickal (b) (4)	09 Mar 2021 17:57:09
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:20
User entered empty.	Brandon Illickal (b) (4)	10 Nov 2020 17:28:15

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:27:05**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Brandon Illickal (b) (4)	27 Apr 2021 18:45:36
DataPoint inactivated with code reason code Data not required.	Brandon Illickal (b) (4)	09 Mar 2021 17:57:09
User entered empty.	System	10 Nov 2020 17:28:15



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**Folder: Adverse Events**

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:24
DataPoint activated with code reason code Data required.	(b) (4) Brandon Illickal (b) (4)	27 Apr 2021 18:45:36
DataPoint inactivated with code reason code Data not required.	Brandon Illickal (b) (4)	09 Mar 2021 17:57:09
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:20
User entered 'Grade 1/Mild (Grade 1/Mild)'	Brandon Illickal (b) (4)	10 Nov 2020 17:28:15

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:24
DataPoint activated with code reason code Data required.	(b) (4) Brandon Illickal (b) (4)	27 Apr 2021 18:45:36
DataPoint inactivated with code reason code Data not required.	Brandon Illickal (b) (4)	09 Mar 2021 17:57:09
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:20
User entered 'No (N)'	Brandon Illickal (b) (4)	10 Nov 2020 17:28:15

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Folder: Adverse Events

Form: Adverse Events (2)

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Death

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:24
	(b) (4)	
DataPoint activated with code reason code Data required.	Brandon Illickal (b) (4)	27 Apr 2021 18:45:36
DataPoint inactivated with code reason code Data not required.	Brandon Illickal (b) (4)	09 Mar 2021 17:57:09
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:20
User entered '0'	Brandon Illickal (b) (4)	10 Nov 2020 17:28:15

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:24
DataPoint activated with code reason code Data required.	(b) (4) Brandon Illickal (b) (4)	27 Apr 2021 18:45:36
DataPoint inactivated with code reason code Data not required.	(b) (4) Brandon Illickal (b) (4)	09 Mar 2021 17:57:09
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:20
User entered '0'	Brandon Illickal (b) (4)	10 Nov 2020 17:28:15

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:24
DataPoint activated with code reason code Data required.	(b) (4) Brandon Illickal (b) (4)	27 Apr 2021 18:45:36
DataPoint inactivated with code reason code Data not required.	(b) (4) Brandon Illickal (b) (4)	09 Mar 2021 17:57:09
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:20
User entered '0'	Brandon Illickal (b) (4)	10 Nov 2020 17:28:15

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Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:24
DataPoint activated with code reason code Data required.	(b) (4) Brandon Illickal (b) (4)	27 Apr 2021 18:45:36
DataPoint inactivated with code reason code Data not required.	Brandon Illickal (b) (4)	09 Mar 2021 17:57:09
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:20
User entered empty.	Brandon Illickal (b) (4)	10 Nov 2020 17:28:15

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:05

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:24
DataPoint activated with code reason code Data required.	(b) (4) Brandon Illickal (b) (4)	27 Apr 2021 18:45:36
DataPoint inactivated with code reason code Data not required.	Brandon Illickal (b) (4)	09 Mar 2021 17:57:09
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:20
User entered empty.	Brandon Illickal (b) (4)	10 Nov 2020 17:28:15

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:27:05**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:24
DataPoint activated with code reason code Data required.	(b) (4) Brandon Illickal (b) (4)	27 Apr 2021 18:45:36
DataPoint inactivated with code reason code Data not required.	Brandon Illickal (b) (4)	09 Mar 2021 17:57:09
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:20
User entered empty.	Brandon Illickal (b) (4)	10 Nov 2020 17:28:15



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Folder: Adverse Events

Form: Adverse Events (2)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:24
DataPoint activated with code reason code Data required.	(b) (4) Brandon Illickal (b) (4)	27 Apr 2021 18:45:36
DataPoint inactivated with code reason code Data not required.	Brandon Illickal (b) (4)	09 Mar 2021 17:57:09
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:20
User entered empty.	Brandon Illickal (b) (4)	10 Nov 2020 17:28:15

US3392149

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:24
DataPoint activated with code reason code Data required.	(b) (4) Brandon Illickal (b) (4)	27 Apr 2021 18:45:36
DataPoint inactivated with code reason code Data not required.	(b) (4) Brandon Illickal (b) (4)	09 Mar 2021 17:57:09
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:20
User entered '0'	Brandon Illickal (b) (4)	10 Nov 2020 17:28:15

US3392149

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:24
	(b) (4)	
DataPoint activated with code reason code Data required.	Brandon Illickal (b) (4)	27 Apr 2021 18:45:36
DataPoint inactivated with code reason code Data not required.	Brandon Illickal (b) (4)	09 Mar 2021 17:57:09
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:20
User entered '0'	Brandon Illickal (b) (4)	10 Nov 2020 17:28:15

US3392149

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:24
	(b) (4)	
DataPoint activated with code reason code Data required.	Brandon Illickal (b) (4)	27 Apr 2021 18:45:36
DataPoint inactivated with code reason code Data not required.	Brandon Illickal (b) (4)	09 Mar 2021 17:57:09
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:20
User entered '0'	Brandon Illickal (b) (4)	10 Nov 2020 17:28:15

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:24
DataPoint activated with code reason code Data required.	(b) (4) Brandon Illickal (b) (4)	27 Apr 2021 18:45:36
DataPoint inactivated with code reason code Data not required.	Brandon Illickal (b) (4)	09 Mar 2021 17:57:09
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:20
User entered 'Not Related (NOT RELATED)'	Brandon Illickal (b) (4)	10 Nov 2020 17:28:15

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:24
DataPoint activated with code reason code Data required.	(b) (4) Brandon Illickal (b) (4)	27 Apr 2021 18:45:36
DataPoint inactivated with code reason code Data not required.	(b) (4) Brandon Illickal (b) (4)	09 Mar 2021 17:57:09
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:20
User entered 'Not Related (NOT RELATED)'	Brandon Illickal (b) (4)	10 Nov 2020 17:28:15

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:05

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:24
DataPoint Un-verified.	(b) (4)	
	Brandon Illickal (b) (4)	27 Apr 2021 18:46:28
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	27 Apr 2021 18:46:28
DataPoint activated with code reason code Data required.	Brandon Illickal (b) (4)	27 Apr 2021 18:45:36
DataPoint inactivated with code reason code Data not required.	Brandon Illickal (b) (4)	09 Mar 2021 17:57:09
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:20
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 17:28:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Nov 2020 17:28:21
User entered 'None (NONE)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	10 Nov 2020 17:28:21
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 17:28:15
User entered empty.	Brandon Illickal (b) (4)	10 Nov 2020 17:28:15

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:05

None

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:24
DataPoint activated with code reason code Data required.	(b) (4) Brandon Illickal (b) (4)	27 Apr 2021 18:45:36
DataPoint inactivated with code reason code Data not required.	(b) (4) Brandon Illickal (b) (4)	09 Mar 2021 17:57:09
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#1) recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 13:18:31
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#1) recorded that matches this AE during this timeframe. Please review and update this field. ' answered with 'DATA UPDATED. DATA ENTRY ERROR.' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 15:58:10
DataPoint Un-verified.	(b) (4), (b) (6)	06 Jan 2021 15:57:08
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Jan 2021 15:57:08
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#1) recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 14:02:32
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:20
User entered '1'	Brandon Illickal (b) (4)	10 Nov 2020 17:28:15



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:24
	(b) (4)	
DataPoint activated with code reason code Data required.	Brandon Illickal (b) (4)	27 Apr 2021 18:45:36
DataPoint inactivated with code reason code Data not required.	Brandon Illickal (b) (4)	09 Mar 2021 17:57:09
DataPoint Un-verified.	(b) (4), (b) (6)	06 Jan 2021 15:57:08
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Jan 2021 15:57:08
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:20
User entered '0'	Brandon Illickal (b) (4)	10 Nov 2020 17:28:15

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:24
	(b) (4)	
DataPoint activated with code reason code Data required.	Brandon Illickal (b) (4)	27 Apr 2021 18:45:36
DataPoint inactivated with code reason code Data not required.	Brandon Illickal (b) (4)	09 Mar 2021 17:57:09
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:20
User entered '0'	Brandon Illickal (b) (4)	10 Nov 2020 17:28:15

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:05

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:24
	(b) (4)	
DataPoint Un-verified.	Brandon Illickal (b) (4)	27 Apr 2021 18:46:50
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	27 Apr 2021 18:46:50
DataPoint activated with code reason code Data required.	Brandon Illickal (b) (4)	27 Apr 2021 18:45:36
DataPoint inactivated with code reason code Data not required.	Brandon Illickal (b) (4)	09 Mar 2021 17:57:09
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:20
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Brandon Illickal (b) (4)	10 Nov 2020 17:28:15

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:27:05**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:24
DataPoint activated with code reason code Data required.	(b) (4) Brandon Illickal (b) (4)	27 Apr 2021 18:45:36
DataPoint inactivated with code reason code Data not required.	(b) (4) Brandon Illickal (b) (4)	09 Mar 2021 17:57:09
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:20
User entered empty.	Brandon Illickal (b) (4)	10 Nov 2020 17:28:15

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:05

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:24
	(b) (4)	
DataPoint activated with code reason code Data required.	Brandon Illickal (b) (4)	27 Apr 2021 18:45:36
DataPoint inactivated with code reason code Data not required.	Brandon Illickal (b) (4)	09 Mar 2021 17:57:09
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:42:20
User entered empty.	Brandon Illickal (b) (4)	10 Nov 2020 17:28:15

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:05

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Brandon Illickal (b) (4)	27 Apr 2021 18:45:36
DataPoint inactivated with code reason code Data not required.	Brandon Illickal (b) (4)	09 Mar 2021 17:57:09
User entered '0'	System	10 Nov 2020 17:28:15

US3392149

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:05

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	27 Apr 2021 18:48:27
DataPoint activated with code reason code Data required.	Brandon Illickal (b) (4)	27 Apr 2021 18:45:36
DataPoint inactivated with code reason code Data not required.	Brandon Illickal (b) (4)	09 Mar 2021 17:57:09
User entered '0'	System	10 Nov 2020 17:28:15

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:27:05**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Brandon Illickal (b) (4)	27 Apr 2021 18:45:36
DataPoint inactivated with code reason code Data not required.	Brandon Illickal (b) (4)	09 Mar 2021 17:57:09



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:27:05

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:25:19
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:43:27
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	28 Sep 2020 19:15:31

US3392149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:27:05

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Mar 2021 07:00:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Mar 2021 07:00:41
Data point term sent to Coder	System	09 Mar 2021 17:38:02
Coding entries removed.	Brandon Illickal (b) (4)	09 Mar 2021 17:36:54
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Mar 2021 00:39:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Mar 2021 00:39:46
Data point term sent to Coder	System	04 Mar 2021 00:38:45
Coding entries removed.	Brandon Illickal (b) (4)	04 Mar 2021 00:37:44

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:27:05

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Mar 2021 00:28:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Mar 2021 00:28:47
Data point term sent to Coder	System	04 Mar 2021 00:28:40
Coding entries removed.	Brandon Illickal (b) (4)	04 Mar 2021 00:27:50
User entered 'zofran' reason for change: Data Entry Error	Brandon Illickal (b) (4)	04 Mar 2021 00:27:50
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: OTHER ANTIEMETICS, PRODUCT: PROMETHAZINE, PRODUCTSYNONYM: PHENERGAN [PROMETHAZINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 21:36:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 21:36:29
Data point term sent to Coder	System	04 Nov 2020 21:20:50
Coding entries removed.	(b) (4), (b) (6)	04 Nov 2020 21:20:33
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PHENOTHIAZINE DERIVATIVES, PRODUCT: PROMETHAZINE, PRODUCTSYNONYM: PHENERGAN [PROMETHAZINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 05:30:50

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:27:05

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	29 Sep 2020 05:30:50
User: (b) (6) - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	28 Sep 2020 19:16:29
User entered 'phenergan'	Brandon Illickal (b) (4)	28 Sep 2020 19:16:06

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:27:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
	(b) (4)	
User entered 'No (N)'	Brandon Illickal (b) (4)	28 Sep 2020 19:16:06

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:27:05

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'NAUSEA, secondary to hepatitis a' reason for change: Data Entry Error	(b) (4) Brandon Illickal (b) (4)	09 Mar 2021 17:36:54
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 06:34:41
Query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' answered with 'DATA CORRECTED' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 21:20:48
User entered 'NAUSEA' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Nov 2020 21:20:33
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 05:54:38
User entered 'hepatitis a'	Brandon Illickal (b) (4)	28 Sep 2020 19:16:06

**US3392149**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:27:05**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered '4' reason for change: Data Entry Error	(b) (4) Brandon Illickal (b) (4)	04 Mar 2021 00:27:50
User entered '25'	(b) (4) Brandon Illickal (b) (4)	28 Sep 2020 19:16:06

US3392149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:27:05

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
	(b) (4)	
User entered 'mg (mg)'	Brandon Illickal (b) (4)	28 Sep 2020 19:16:06



US3392149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:27:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	28 Sep 2020 19:16:06

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:27:05

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User closed query 'Per CDM: Please clarify if it is possible to select from dropdown "Four times daily" instead of writing "Every 6 hour as needed". Thank you! ' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Mar 2021 15:21:29
Query 'Per CDM: Please clarify if it is possible to select from dropdown "Four times daily" instead of writing "Every 6 hour as needed". Thank you! ' answered with 'data corrected' (Site from DM).	Brandon Illickal (b) (4)	17 Mar 2021 15:23:45
User entered 'four times daily (QID)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	17 Mar 2021 15:23:30
User opened query 'Per CDM: Please clarify if it is possible to select from dropdown "Four times daily" instead of writing "Every 6 hour as needed". Thank you! ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 11:11:40
User entered 'other (OTHER)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	04 Mar 2021 00:37:44
User entered 'three times daily (TID)'	Brandon Illickal (b) (4)	28 Sep 2020 19:16:06

US3392149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:27:05

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
	(b) (4)	
User entered empty; reason for change Data Entry Error	Brandon Illickal (b) (4)	17 Mar 2021 15:23:30
User entered 'every 6 hour as needed' reason for change: Data Entry Error	Brandon Illickal (b) (4)	04 Mar 2021 00:37:44
User entered empty.	Brandon Illickal (b) (4)	28 Sep 2020 19:16:06

**US3392149**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:27:05**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4) Brandon Illickal (b) (4)	04 Mar 2021 00:37:44
User entered 'Oral (ORAL)'	Brandon Illickal (b) (4)	28 Sep 2020 19:16:06

US3392149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:27:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
	(b) (4)	
User entered 'sublingual' reason for change: Data Entry Error	Brandon Illickal (b) (4)	04 Mar 2021 00:37:44
User entered empty.	Brandon Illickal (b) (4)	28 Sep 2020 19:16:06

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:27:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
	(b) (4)	
User entered '24 Sep 2020'	Brandon Illickal (b) (4)	28 Sep 2020 19:16:06

**US3392149**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:27:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
	(b) (4)	
User entered '0'	Brandon Illickal (b) (4)	28 Sep 2020 19:16:06

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:27:05

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Mar 2021 14:41:09
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'medication stop date corrected' (Site from DM).	Brandon Illickal (b) (4)	04 Mar 2021 00:15:51
User entered 'No (N)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	04 Mar 2021 00:15:35
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	07 Feb 2021 12:01:09
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	28 Sep 2020 19:16:06



US3392149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:27:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
	(b) (4)	
User entered '24 Sep 2020' reason for change: Data Entry Error	Brandon Illickal (b) (4)	04 Mar 2021 00:27:38
User entered '25 Sep 2020' reason for change: Data Entry Error	Brandon Illickal (b) (4)	04 Mar 2021 00:15:35
User entered empty.	Brandon Illickal (b) (4)	28 Sep 2020 19:16:06

**US3392149**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:27:05**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
	(b) (4)	
User entered 'No (N)'	Brandon Illickal (b) (4)	28 Sep 2020 19:16:06

**US3392149**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:27:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	17 Mar 2021 15:23:30
User entered empty.	System	04 Mar 2021 00:37:44
User entered '3'	System	28 Sep 2020 19:16:06

**US3392149**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:27:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Mar 2021 15:23:30
User entered empty.	System	04 Mar 2021 00:37:44
User entered '1'	System	28 Sep 2020 19:16:06

**US3392149**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:27:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Mar 2021 15:23:30
User entered empty.	System	04 Mar 2021 00:37:44
User entered '804 (804)'	System	28 Sep 2020 19:16:06

US3392149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:27:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:12
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Jan 2021 20:36:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Jan 2021 20:36:31
Data point term sent to Coder	System	04 Jan 2021 20:35:35
Coding entries removed.	(b) (4), (b) (6)	04 Jan 2021 20:35:20
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 21:42:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 21:42:51
Data point term sent to Coder	System	10 Nov 2020 21:42:17
Coding entries removed.	Brandon Illickal (b) (4)	10 Nov 2020 21:41:23
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 21:28:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 21:28:29
Data point term sent to Coder	System	04 Nov 2020 21:14:43
Data point term sent to Coder	System	04 Nov 2020 21:12:41
User entered 'TYLENOL'	(b) (4), (b) (6)	04 Nov 2020 21:12:20

**US3392149**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:27:05**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:12
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:12:20

US3392149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:27:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:12
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE & INJECTION SITE PAIN are considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reactions of HEADACHE & INJECTION SITE PAIN did not meet the AE reporting criteria. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Feb 2021 15:32:44
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE & INJECTION SITE PAIN are considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reactions of HEADACHE & INJECTION SITE PAIN did not meet the AE reporting criteria. ' answered with 'INJECTION SITE PAIN; HEADACHE does not meet AE reporting criteria' (Site from DM).	Brandon Illickal (b) (4)	11 Feb 2021 09:58:04



US3392149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:27:05

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE & INJECTION SITE PAIN are considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reactions of HEADACHE & INJECTION SITE PAIN did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 14:31:17
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the DIARY DOSE 1; DAY 3, 4 is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of DIARY DOSE 1; DAY 3, 4 did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 15:43:09
User closed query 'Per DM CLR: Please specify the actual symptoms recorded in the diary (e.g. INJECTION SITE PAIN, HEADACHE etc.). Update and reconcile with AE eCRF if it fits the protocol specified criteria for AE reporting. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 15:42:43

US3392149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:27:05

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the DIARY DOSE 1; DAY 3, 4 is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of DIARY DOSE 1; DAY 3, 4 did not meet the AE reporting criteria.' answered with 'DATA UPDATED. DATA ENTRY ERROR.' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 20:35:45
Query 'Per DM CLR: Please specify the actual symptoms recorded in the diary (e.g. INJECTION SITE PAIN, HEADACHE etc.). Update and reconcile with AE eCRF if it fits the protocol specified criteria for AE reporting. Otherwise, clarify. ' answered with 'DATA UPDATED. DATA ENTRY ERROR.' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 20:35:41
User entered 'INJECTION SITE PAIN; HEADACHE' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Jan 2021 20:35:20
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the DIARY DOSE 1; DAY 3, 4 is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of DIARY DOSE 1; DAY 3, 4 did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 06:20:45

US3392149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:27:05

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please specify the actual symptoms recorded in the diary (e.g. INJECTION SITE PAIN, HEADACHE etc.). Update and reconcile with AE eCRF if it fits the protocol specified criteria for AE reporting. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 06:20:33
User entered 'Diary dose 1; Day 3,4' reason for change: Data Entry Error	Brandon Illickal (b) (4)	10 Nov 2020 21:41:23
User entered 'TYLENOL TAKEN FOR PAIN AND FEVER AT POST VACCINE DAY 1'	(b) (4), (b) (6)	04 Nov 2020 21:12:20

**US3392149**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:27:05**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:12
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered '500'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:12:20

**US3392149**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:27:05**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:12
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:12:20

**US3392149**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:27:05**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:12
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:12:20

US3392149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:27:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:12
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	(b) (4)	
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	10 Nov 2020 21:40:17
User entered 'as needed (PRN)' reason for change: Data Entry Error	System	10 Nov 2020 21:40:17
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	Brandon Illickal (b) (4)	10 Nov 2020 21:40:17
User entered 'once (ONCE)' reason for change: Data Entry Error	(b) (4)	10 Nov 2020 21:40:02
User entered 'as needed (PRN)'	(b) (4), (b) (6)	04 Nov 2020 21:12:20

**US3392149**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:27:05**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:12
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:12:20



US3392149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:27:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:12
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Nov 2020 21:14:14
User entered 'Oral (ORAL)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Nov 2020 21:14:14
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Nov 2020 21:12:20
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 21:12:20

**US3392149**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:27:05**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:12
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:12:20

**US3392149**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:12
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered '04 Sep 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:14:03
User entered '02 Sep 2020'	(b) (4), (b) (6)	04 Nov 2020 21:12:20

**US3392149**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:27:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:12
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:12:20

**US3392149**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:27:05**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:12
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:12:20

US3392149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:27:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:12
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	(b) (4)	04 Nov 2020 21:14:03
User entered '05 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Nov 2020 21:14:03
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	04 Nov 2020 21:12:20
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 21:12:20

US3392149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:27:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:12
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User closed query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Jan 2021 15:43:21
Query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response.' answered with 'DATA UPDATED. DATA ENTRY ERROR.' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 20:35:50
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Jan 2021 20:35:26
User opened query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 06:21:11
User entered 'No (N)'	(b) (4), (b) (6)	04 Nov 2020 21:12:20

**US3392149**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:27:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:12
User entered empty.	System	04 Nov 2020 21:12:20



**US3392149**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:27:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:12
User entered empty.	System	04 Nov 2020 21:12:20

**US3392149**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:27:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:12
User entered empty.	System	04 Nov 2020 21:12:20

US3392149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:27:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:16
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE SODIUM SESQUIHYDRATE, PRODUCTSYNONYM: PROTONIX [PANTOPRAZOLE SODIUM SESQUIHYDRATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 09:41:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 09:41:30
Data point term sent to Coder	System	09 Mar 2021 17:49:10
User entered 'protonix'	Brandon Illickal (b) (4)	09 Mar 2021 17:48:55

**US3392149**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:27:05**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:16
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'No (N)'	(b) (4) Brandon Illickal (b) (4)	09 Mar 2021 17:48:55

**US3392149**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:27:05**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:16
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'gastroesophageal reflux disease, secondary to hepatitis a'	(b) (4) Brandon Illickal (b) (4)	09 Mar 2021 17:48:55

**US3392149**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:27:05**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:16
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered '20'	(b) (4) Brandon Illickal (b) (4)	09 Mar 2021 17:48:55

**US3392149**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:27:05**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:16
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'mg (mg)'	(b) (4) Brandon Illickal (b) (4)	09 Mar 2021 17:48:55

US3392149

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:27:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:16
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered empty.	(b) (4)	09 Mar 2021 17:48:55
	Brandon Illickal (b) (4)	



**US3392149**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:27:05**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:16
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'once (ONCE)'	(b) (4)	09 Mar 2021 17:48:55
	Brandon Illickal (b) (4)	

**US3392149**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:27:05**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:16
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered empty.	(b) (4)	09 Mar 2021 17:48:55

**US3392149**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:27:05**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:16
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Oral (ORAL)'	(b) (4)	09 Mar 2021 17:48:55

**US3392149**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:27:05**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:16
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered empty.	(b) (4)	09 Mar 2021 17:48:55

**US3392149**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:27:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:16
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered '24 Sep 2020'	(b) (4) Brandon Illickal (b) (4)	09 Mar 2021 17:48:55

**US3392149**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:27:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:16
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered '0'	(b) (4) Brandon Illickal (b) (4)	09 Mar 2021 17:48:55

**US3392149**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:27:05**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:16
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'No (N)'	(b) (4) Brandon Illickal (b) (4)	09 Mar 2021 17:48:55

**US3392149**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:27:05**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:16
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered '24 Sep 2020'	(b) (4)	09 Mar 2021 17:48:55



**US3392149**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:27:05**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:16
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'No (N)'	(b) (4) Brandon Illickal (b) (4)	09 Mar 2021 17:48:55

**US3392149**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:27:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:16
User entered empty.	System	09 Mar 2021 17:48:55

**US3392149**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:27:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:16
User entered empty.	System	09 Mar 2021 17:48:55

**US3392149**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:27:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:01:16
User entered empty.	System	09 Mar 2021 17:48:55

US3392149

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:27:05

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:25:19
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User closed query 'Per CDM: Please ensure Labs reported on SAE narrative are reported under Con Proc. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:16:33
Query 'Per CDM: Please ensure Labs reported on SAE narrative are reported under Con Proc. Thank you' answered with 'Added Labs to Con Proc' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 21:13:15
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 21:11:22
User opened query 'Per CDM: Please ensure Labs reported on SAE narrative are reported under Con Proc. Thank you' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 14:33:59
User entered 'No (N)'	Brandon Illickal (b) (4)	28 Sep 2020 19:15:24

**US3392149**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 09 Jun 2021 17:27:05**

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered '24 Sep 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:13:34
User entered '23 Sep 2020'	(b) (4), (b) (6)	07 Apr 2021 21:12:57

US3392149

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:27:05

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Chemistry Labs'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:12:57

**US3392149**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 09 Jun 2021 17:27:05**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:12:57



**US3392149**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 09 Jun 2021 17:27:05**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:12:57

US3392149

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:27:05

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:54:34
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:06

US3392149

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:27:05

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:54:34
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Hematology Labs'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:06

US3392149

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:27:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:54:34
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:06

US3392149

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:27:05

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:54:34
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:06

**US3392149**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 09 Jun 2021 17:27:05**

**Procedure/Surgery date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:54:38
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:44

**US3392149**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 09 Jun 2021 17:27:05**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:54:38
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Coagulation'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:44

**US3392149**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 09 Jun 2021 17:27:05**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:54:38
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:44



US3392149

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:27:05

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:54:38
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:44

**US3392149**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (4)**

**Generated On: 09 Jun 2021 17:27:05**

**Procedure/Surgery date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:54:41
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered '25 Sep 2020'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:15:16

**US3392149**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (4)**

**Generated On: 09 Jun 2021 17:27:05**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:54:41
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Ultrasound'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:15:16

**US3392149**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (4)**

**Generated On: 09 Jun 2021 17:27:05**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:54:41
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:15:16

US3392149

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:27:05

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:54:41
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:15:16

US3392149

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:27:05

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:09:34
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User closed query 'Per CDM: AE start date is marked 24Sep2020 and end date is 25Sep2020, however "Date of dosing discontinuation" is 06Oct2020. Please clarify why dosing discontinuation was later than actual AE start date and end date and if necessary update the dates or clarify. Thank you!' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Jan 2021 14:27:28
Query 'Per CDM: AE start date is marked 24Sep2020 and end date is 25Sep2020, however "Date of dosing discontinuation" is 06Oct2020. Please clarify why dosing discontinuation was later than actual AE start date and end date and if necessary update the dates or clarify. Thank you!' answered with 'Decision to was made at subject study visit' (Site from DM).	Brandon Illickal (b) (4)	14 Jan 2021 01:49:39
User opened query 'Per CDM: AE start date is marked 24Sep2020 and end date is 25Sep2020, however "Date of dosing discontinuation" is 06Oct2020. Please clarify why dosing discontinuation was later than actual AE start date and end date and if necessary update the dates or clarify. Thank you!' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 08:24:11
User entered '06 Oct 2020'	Brandon Illickal (b) (4)	09 Dec 2020 22:45:39

US3392149

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:27:05

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:09:34
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
Query 'Per CDM: Subject discontinued dosing because of SAE. Please confirm if subject stays in follow-up or subject discontinued study. If subject discontinued study, then please consider adding information also under "End of Study/Study Discontinuation" form. Thank you!' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Jan 2021 09:28:32
User opened query 'Per CDM: Subject discontinued dosing because of SAE. Please confirm if subject stays in follow-up or subject discontinued study. If subject discontinued study, then please consider adding information also under "End of Study/Study Discontinuation" form. Thank you!' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 09:22:39
User entered 'SAE (specify) (SAE)'	Brandon Illickal (b) (4)	09 Dec 2020 22:45:39

US3392149

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:27:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:09:34
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:18:01
User closed query 'Per CDM: Per sponsor review, please update specify field to include only AE, number sign, and number. (i.e. AE #1).' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 13:57:09
Query 'Per CDM: Per sponsor review, please update specify field to include only AE, number sign, and number. (i.e. AE #1).' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 17:49:40
User entered 'AE #1' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 17:49:34
User opened query 'Per CDM: Per sponsor review, please update specify field to include only AE, number sign, and number. (i.e. AE #1).' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 19:44:20
User closed query 'Per CDM Re-query: Thank you for your response. However, per CCGs, please record the exact AE LOGLINE #. ' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 17:02:17
Query 'Per CDM Re-query: Thank you for your response. However, per CCGs, please record the exact AE LOGLINE #. ' answered with 'GOT IT, THANK YOU FOR THE CLARIFICATION!' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 16:56:14
User entered 'AE LOG LINE #1' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Jan 2021 16:55:54
User opened query 'Per CDM Re-query: Thank you for your response. However, per CCGs, please record the exact AE LOGLINE #. ' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 16:20:06
User closed query "Per CDM: please record SAE record number (i.e. AE #1, etc.) instead of details' . ' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 16:20:06
Query "Per CDM: please record SAE record number (i.e. AE #1, etc.) instead of details' . ' answered with 'DATA UPDATED. DATA ENTRY ERROR.' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 18:13:05



US3392149

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:27:05

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

Audit	User	Time (GMT)
User entered 'USA-US119-2020-MRNA-1273-P301000003' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Jan 2021 18:12:52
User opened query "Per CDM: please record SAE record number (i.e. AE #1, etc.) instead of details'.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 07:03:42
User entered 'Hepatitis a'	Brandon Illickal (b) (4)	09 Dec 2020 22:45:39

**US3392149**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:27:05**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered	System	29 Sep 2020 14:13:47
'USA-US119-2020-MRNA-1273-P301000003'		

**US3392149**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:27:05**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'Yes (Y)'	System	29 Sep 2020 14:13:47

**US3392149**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:27:05**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'No (N)'	System	29 Sep 2020 14:13:47

**US3392149**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:27:05**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'No (N)'	System	29 Sep 2020 14:13:47

**US3392149**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:27:05**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'Yes (Y)'	System	29 Sep 2020 14:13:47

US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'No (N)'	System	29 Sep 2020 14:13:47

US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'No (N)'	System	29 Sep 2020 14:13:47



US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'No (N)'	System	29 Sep 2020 14:13:47

US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'Michael'	System	29 Sep 2020 14:13:47

US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'Cotugno'	System	29 Sep 2020 14:13:47

US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:05

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 17:17:10
User entered 'US'	System	29 Sep 2020 14:14:12

**US3392149**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:27:05**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	14 Apr 2021 17:04:29
User entered '6'	System	10 Mar 2021 16:20:24
User entered '5'	System	07 Jan 2021 17:49:38
User entered '4'	System	11 Nov 2020 13:02:53
User entered '3'	System	09 Nov 2020 15:45:49
User entered '2'	System	02 Oct 2020 17:17:18
User entered '1'	System	29 Sep 2020 14:14:12

**US3392149**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:27:05**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'USA-US119-2020-MRNA-1273-P301000003'	System	29 Sep 2020 14:13:47

**US3392149**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:27:05**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'Yes (Y)'	System	29 Sep 2020 14:13:47

US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:05

Death

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'No (N)'	System	29 Sep 2020 14:13:47



**US3392149**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:27:05**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'No (N)'	System	29 Sep 2020 14:13:47

**US3392149**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:27:05**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'Yes (Y)'	System	29 Sep 2020 14:13:47

US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'No (N)'	System	29 Sep 2020 14:13:47

US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'No (N)'	System	29 Sep 2020 14:13:47

US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'No (N)'	System	29 Sep 2020 14:13:47

US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'Michael'	System	29 Sep 2020 14:13:47

US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'Cotugno'	System	29 Sep 2020 14:13:47

US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:05

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 17:17:10
User entered 'US'	System	29 Sep 2020 14:14:12



**US3392149**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:27:05**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	14 Apr 2021 17:04:29
User entered '6'	System	10 Mar 2021 16:20:24
User entered '5'	System	07 Jan 2021 17:49:38
User entered '4'	System	11 Nov 2020 13:02:53
User entered '3'	System	09 Nov 2020 15:45:49
User entered '2'	System	02 Oct 2020 17:17:18
User entered '1'	System	29 Sep 2020 14:14:12

**US3392149**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 17:27:05**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:41:12
User entered '29/Sep/2020 10:14'	System	29 Sep 2020 14:14:12

US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:27:05

**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.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 17:17:10
User entered 'I'	(b) (4), (b) (6)	29 Sep 2020 14:14:12

**US3392149**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:27:05**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered	System	29 Sep 2020 14:13:47
'USA-US119-2020-MRNA-1273-P301000003'		

**US3392149**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:27:05**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'Yes (Y)'	System	29 Sep 2020 14:13:47

**US3392149**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:27:05**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'No (N)'	System	29 Sep 2020 14:13:47

US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'No (N)'	System	29 Sep 2020 14:13:47

**US3392149**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:27:05**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'Yes (Y)'	System	29 Sep 2020 14:13:47



**US3392149**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:27:05**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'No (N)'	System	29 Sep 2020 14:13:47

**US3392149**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:27:05**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'No (N)'	System	29 Sep 2020 14:13:47

US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'No (N)'	System	29 Sep 2020 14:13:47

US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'Michael'	System	29 Sep 2020 14:13:47

US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'Cotugno'	System	29 Sep 2020 14:13:47

US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:05

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 17:17:10
User entered 'US'	System	29 Sep 2020 14:14:12

**US3392149**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:27:05**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	14 Apr 2021 17:04:29
User entered '6'	System	10 Mar 2021 16:20:24
User entered '5'	System	07 Jan 2021 17:49:38
User entered '4'	System	11 Nov 2020 13:02:53
User entered '3'	System	09 Nov 2020 15:45:49
User entered '2'	System	02 Oct 2020 17:17:18
User entered '1'	System	29 Sep 2020 14:14:12

**US3392149**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 17:27:05**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:41:12
User entered '02/Oct/2020 13:17'	System	02 Oct 2020 17:17:18



US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:27:05

**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.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 13:02:43
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:41:12
User entered 'I'	(b) (4), (b) (6)	02 Oct 2020 17:17:18

**US3392149**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:27:05**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'USA-US119-2020-MRNA-1273-P301000003'	System	29 Sep 2020 14:13:47

**US3392149**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:27:05**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'Yes (Y)'	System	29 Sep 2020 14:13:47

**US3392149**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:27:05**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'No (N)'	System	29 Sep 2020 14:13:47

**US3392149**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:27:05**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'No (N)'	System	29 Sep 2020 14:13:47

**US3392149**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:27:05**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'Yes (Y)'	System	29 Sep 2020 14:13:47

US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'No (N)'	System	29 Sep 2020 14:13:47

US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'No (N)'	System	29 Sep 2020 14:13:47



US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'No (N)'	System	29 Sep 2020 14:13:47

US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'Michael'	System	29 Sep 2020 14:13:47

US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'Cotugno'	System	29 Sep 2020 14:13:47

US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:05

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 17:17:10
User entered 'US'	System	29 Sep 2020 14:14:12

**US3392149**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:27:05**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	14 Apr 2021 17:04:29
User entered '6'	System	10 Mar 2021 16:20:24
User entered '5'	System	07 Jan 2021 17:49:38
User entered '4'	System	11 Nov 2020 13:02:53
User entered '3'	System	09 Nov 2020 15:45:49
User entered '2'	System	02 Oct 2020 17:17:18
User entered '1'	System	29 Sep 2020 14:14:12

**US3392149**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 17:27:05**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:41:12
User entered '09/Nov/2020 10:45'	System	09 Nov 2020 15:45:49

US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:27:05

**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.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 13:02:43
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:41:12
User entered 'I'	(b) (4), (b) (6)	09 Nov 2020 15:45:49

**US3392149**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:27:05**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'USA-US119-2020-MRNA-1273-P301000003'	System	29 Sep 2020 14:13:47



**US3392149**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:27:05**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'Yes (Y)'	System	29 Sep 2020 14:13:47

**US3392149**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:27:05**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'No (N)'	System	29 Sep 2020 14:13:47

US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'No (N)'	System	29 Sep 2020 14:13:47

**US3392149**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:27:05**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'Yes (Y)'	System	29 Sep 2020 14:13:47

US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'No (N)'	System	29 Sep 2020 14:13:47

US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'No (N)'	System	29 Sep 2020 14:13:47

US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'No (N)'	System	29 Sep 2020 14:13:47

US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'Michael'	System	29 Sep 2020 14:13:47



US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'Cotugno'	System	29 Sep 2020 14:13:47

US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:05

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 17:17:10
User entered 'US'	System	29 Sep 2020 14:14:12

**US3392149**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:27:05**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	14 Apr 2021 17:04:29
User entered '6'	System	10 Mar 2021 16:20:24
User entered '5'	System	07 Jan 2021 17:49:38
User entered '4'	System	11 Nov 2020 13:02:53
User entered '3'	System	09 Nov 2020 15:45:49
User entered '2'	System	02 Oct 2020 17:17:18
User entered '1'	System	29 Sep 2020 14:14:12

**US3392149**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 17:27:05**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered '11/Nov/2020 13:02'	(b) (4) System	11 Nov 2020 13:02:53

US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:27:05

**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.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:49:27
User entered 'I'	(b) (4), (b) (6)	11 Nov 2020 13:02:53

**US3392149**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:27:05**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'USA-US119-2020-MRNA-1273-P301000003'	System	29 Sep 2020 14:13:47

**US3392149**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:27:05**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'Yes (Y)'	System	29 Sep 2020 14:13:47

**US3392149**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:27:05**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'No (N)'	System	29 Sep 2020 14:13:47



US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'No (N)'	System	29 Sep 2020 14:13:47

**US3392149**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:27:05**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'Yes (Y)'	System	29 Sep 2020 14:13:47

US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'No (N)'	System	29 Sep 2020 14:13:47

US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'No (N)'	System	29 Sep 2020 14:13:47

US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'No (N)'	System	29 Sep 2020 14:13:47

US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'Michael'	System	29 Sep 2020 14:13:47

US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'Cotugno'	System	29 Sep 2020 14:13:47

US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:05

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 17:17:10
User entered 'US'	System	29 Sep 2020 14:14:12



**US3392149**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:27:05**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	14 Apr 2021 17:04:29
User entered '6'	System	10 Mar 2021 16:20:24
User entered '5'	System	07 Jan 2021 17:49:38
User entered '4'	System	11 Nov 2020 13:02:53
User entered '3'	System	09 Nov 2020 15:45:49
User entered '2'	System	02 Oct 2020 17:17:18
User entered '1'	System	29 Sep 2020 14:14:12

**US3392149**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (5)**

**Generated On: 09 Jun 2021 17:27:05**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered '07/Jan/2021 17:49'	(b) (4) System	07 Jan 2021 17:49:38

US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:27:05

**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.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 16:20:05
User entered 'I'	(b) (4), (b) (6)	07 Jan 2021 17:49:38

**US3392149**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:27:05**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered	System	29 Sep 2020 14:13:47
'USA-US119-2020-MRNA-1273-P301000003'		

**US3392149**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:27:05**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'Yes (Y)'	System	29 Sep 2020 14:13:47

US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:05

Death

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'No (N)'	System	29 Sep 2020 14:13:47

US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'No (N)'	System	29 Sep 2020 14:13:47

**US3392149**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:27:05**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'Yes (Y)'	System	29 Sep 2020 14:13:47



US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'No (N)'	System	29 Sep 2020 14:13:47

US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'No (N)'	System	29 Sep 2020 14:13:47

**US3392149**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:27:05**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'No (N)'	System	29 Sep 2020 14:13:47

US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'Michael'	System	29 Sep 2020 14:13:47

US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'Cotugno'	System	29 Sep 2020 14:13:47

US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:05

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 17:17:10
User entered 'US'	System	29 Sep 2020 14:14:12

**US3392149**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:27:05**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	14 Apr 2021 17:04:29
User entered '6'	System	10 Mar 2021 16:20:24
User entered '5'	System	07 Jan 2021 17:49:38
User entered '4'	System	11 Nov 2020 13:02:53
User entered '3'	System	09 Nov 2020 15:45:49
User entered '2'	System	02 Oct 2020 17:17:18
User entered '1'	System	29 Sep 2020 14:14:12

**US3392149**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (6)**

**Generated On: 09 Jun 2021 17:27:05**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered '10/Mar/2021 10:20'	(b) (4) System	10 Mar 2021 16:20:24



US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:27:05

**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.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:04:36
User entered 'I'	(b) (4), (b) (6)	10 Mar 2021 16:20:24

**US3392149**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:27:05**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered	System	29 Sep 2020 14:13:47
'USA-US119-2020-MRNA-1273-P301000003'		

**US3392149**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:27:05**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'Yes (Y)'	System	29 Sep 2020 14:13:47

**US3392149**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:27:05**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'No (N)'	System	29 Sep 2020 14:13:47

US3392149

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Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'No (N)'	System	29 Sep 2020 14:13:47

**US3392149**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:27:05**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'Yes (Y)'	System	29 Sep 2020 14:13:47

US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'No (N)'	System	29 Sep 2020 14:13:47

US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'No (N)'	System	29 Sep 2020 14:13:47



US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'No (N)'	System	29 Sep 2020 14:13:47

US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'Michael'	System	29 Sep 2020 14:13:47

US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:14:06
User entered 'Cotugno'	System	29 Sep 2020 14:13:47

**US3392149**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:27:05**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:41:12
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 17:17:10
User entered 'US'	System	29 Sep 2020 14:14:12

**US3392149**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:27:05**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	14 Apr 2021 17:04:29
User entered '6'	System	10 Mar 2021 16:20:24
User entered '5'	System	07 Jan 2021 17:49:38
User entered '4'	System	11 Nov 2020 13:02:53
User entered '3'	System	09 Nov 2020 15:45:49
User entered '2'	System	02 Oct 2020 17:17:18
User entered '1'	System	29 Sep 2020 14:14:12

**US3392149**

**Folder: SAE USA-US119-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (7)**

**Generated On: 09 Jun 2021 17:27:05**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
User entered '14/Apr/2021 13:04'	(b) (4) System	14 Apr 2021 17:04:29

US3392149

Folder: SAE USA-US119-2020-MRNA-1273-P301000003

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 17:27:05

**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.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:23
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 17:04:36
User entered 'I'	(b) (4), (b) (6)	14 Apr 2021 17:04:29