

US3342088 (Prod: Tekton Research- Austin)

Generated By: (b) (6)

Generated On: 26 Nov 2020 10:58:33

All time stamps listed in this document are displayed in GMT

US3342088

Form: Participant Creation

Generated On: 26 Nov 2020 10:58:33

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[Participant ID](#)

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

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US3342088

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:58:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 AUG 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

Generated On: 26 Nov 2020 10:58:33

Date of Birth (MMM yyyy)	(b) (6) 1970
Age	50
Age Units	YEARS
Age (Derived)	50
Sex	Female <input checked="" type="radio"/> Male <input 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

Generated On: 26 Nov 2020 10:58:33

Date of Informed Consent ( <i>dd MMM yyyy</i> )	17 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input 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

Generated On: 26 Nov 2020 10:58:33

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:58:33

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:58:33

Condition	SULFA DRUG ALLERGY (RASH)
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:58:33

Condition	TARSAL TUNNEL SYNDROME RIGHT FOOT
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:58:33

Condition	TARSAL TUNNEL SURGERY RIGHT FOOT
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:58:33

Condition	LEFT ARM MINOR BURN
Start date (dd MMM yyyy)	12 AUG 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:33

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	17 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	15:31 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 15:31
Height ( <i>xxx.x</i> )	165.0 cm
Weight ( <i>xxx.x</i> )	84.5 kg
BMI ( <i>xxx.x</i> )	31.03765 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

Generated On: 26 Nov 2020 10:58:33

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 AUG 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: Childbearing Potential

Generated On: 26 Nov 2020 10:58:33

Date of assessment (*dd MMM yyyy*) 17 AUG 2020

Is the participant of childbearing potential? Yes ☒ No ☐

If No, what is the reason? Surgically sterile ☐  
Post-menopausal ☐  
Partner medically sterile ☐  
Not reached age of Menarche ☐  
Other ☐

If Partner medically sterile or Other, specify \_\_\_\_\_

If Surgically sterile, date of surgery (*dd MMM yyyy*) \_\_\_\_\_

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) \_\_\_\_\_

Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:58:33

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	17 AUG 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:58:33

**Occupational Risk**

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers) Yes ☐ No ☒

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers) Yes ☐ No ☒

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores) Yes ☐ No ☒

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants) Yes ☐ No ☒

**Warehouse shipping and fulfillment centers** and jobs (e.g., Amazon facilities) Yes ☐ No ☒

**Transportation and delivery services** (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers) Yes ☐ No ☒

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing) Yes ☐ No ☒

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services) Yes ☐ No ☒

**Hospitality and Tourism Workers** (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts) Yes ☐ No ☒

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy) Yes ☒ No ☐

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting) Yes ☐ No ☒

**Other** Yes ☐ No ☒

**Specify**

**Location and Living Circumstances Risk (check all that apply)**

**No Risk Identified** False

**Resides in Nursing Home or Assisted Living Facility** False

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs) True



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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:58:33

<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)	False
<b>Other</b>	False
<b>Specify</b>	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:58:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 AUG 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

Generated On: 26 Nov 2020 10:58:33

What was the date of randomization? (dd MMM yyyy) 17 AUG 2020

What was the participant's randomization number? 105305

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

Generated On: 26 Nov 2020 10:58:33

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:33

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)	17 AUG 2020
Time of assessment (00:00-23:59)	15:31 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 15:31
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 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: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:58:33

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)	17 AUG 2020
Time of assessment (00:00-23:59)	17:27 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 17:27
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:58:33

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:58:33

Was the pregnancy test performed? Yes ☐  
No ☒

Date of test (*dd MMM yyyy*) \_\_\_\_\_

Test performed Urine ☐  
Serum ☐

Result Positive ☐  
Negative ☐

Was FSH sample collected? Yes ☐  
No ☐

Collection date \_\_\_\_\_

Collection time \_\_\_\_\_

Collection date and time (derived) \_\_\_\_\_



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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:58:33

Was study treatment given?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, reason not given	Participant declined due to Adverse Event <input type="radio"/>
	Physician withheld dose due to Adverse Event <input type="radio"/>
	Death <input type="radio"/>
	Lost To Follow-Up <input type="radio"/>
	Physician Decision <input type="radio"/>
	Pregnancy <input type="radio"/>
	Protocol Deviation <input type="radio"/>
	Study Terminated by Sponsor <input type="radio"/>
	Withdrawal of Consent by Participant <input type="radio"/>
	Confirmed COVID-19 <input type="radio"/>
	Other <input type="radio"/>
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)	17 AUG 2020
What was the treatment time? (00:00-23:59)	16:57 (24 HR)
Treatment Date and Time (derived)	17 AUG 2020 16:57
Which arm was used to give treatment?	Left Arm <input type="radio"/>
	Right Arm <input checked="" type="radio"/>
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

Generated On: 26 Nov 2020 10:58:33

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	17 AUG 2020
Collection time ( <i>00:00-23:59</i> )	16:33 (24 HR)
Collection date and time (derived)	17 AUG 2020 16:33

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:58:33

Collection date ( <i>dd MMM yyyy</i> )			17 AUG 2020
Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:35	17 AUG 2020 16:35
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:58:33

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: 26 Nov 2020 10:58:33

**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

98.2 °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 17 AUG 2020 17:29

PC Open Date & Time 17 AUG 2020 17:17

PC Close Date & Time 17 AUG 2020 19:47

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:58:33

**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	17 AUG 2020 21:32
PC Open Date & Time	17 AUG 2020 20:42
PC Close Date & Time	18 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:58:33

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**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

98.2 °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

18 AUG 2020 12:02

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PC Open Date & Time

18 AUG 2020 12:00

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PC Close Date & Time

19 AUG 2020 11:59

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US3342088

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:58:33

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**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

97.2 °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

19 AUG 2020 12:37

---

PC Open Date & Time

19 AUG 2020 12:00

---

PC Close Date & Time

20 AUG 2020 11:59

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US3342088

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:58:33

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**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

98.2 °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

20 AUG 2020 12:38

---

PC Open Date & Time

20 AUG 2020 12:00

---

PC Close Date & Time

21 AUG 2020 11:59

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US3342088

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:58:33

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 AUG 2020 12:01

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:58:33

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**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

98.4 °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

22 AUG 2020 12:01

---

PC Open Date & Time

22 AUG 2020 12:00

---

PC Close Date & Time

23 AUG 2020 11:59

---

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:58:33

---

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

98.2 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

23 AUG 2020 12:11

---

PC Open Date & Time

23 AUG 2020 12:00

---

PC Close Date & Time

24 AUG 2020 11:59

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US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:58:33

**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

17 AUG 2020 17:30

PC Open Date & Time

17 AUG 2020 17:17

PC Close Date & Time

17 AUG 2020 19:47

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:58:33

**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

17 AUG 2020 21:33

PC Open Date & Time

17 AUG 2020 20:42

PC Close Date & Time

18 AUG 2020 11:59

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:58:33

**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

18 AUG 2020 12:02

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:58:33

**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

19 AUG 2020 12:38

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59



US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:58:33

**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

20 AUG 2020 12:39

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:58:33

**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

21 AUG 2020 12:02

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:58:33

**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

22 AUG 2020 12:01

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:58:33

**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

23 AUG 2020 12:11

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:58:33

**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 ☐

US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:58:33

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

No ☒

Yes ☐

PC Time stamp	17 AUG 2020 17:30
PC Open Date & Time	17 AUG 2020 17:17
PC Close Date & Time	17 AUG 2020 19:47

US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:58:33

**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 ☐

US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:58:33

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

No ☒

Yes ☐

PC Time stamp	17 AUG 2020 21:33
PC Open Date & Time	17 AUG 2020 20:42
PC Close Date & Time	18 AUG 2020 11:59



US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:58:33

**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 ☒

US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:58:33

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 12:03
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:58:33

**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 ☒

US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:58:33

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 12:38
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:58:33

**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 ☒

US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:58:33

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 12:39
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:58:33

**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 ☒

US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:58:33

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 12:03
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59



US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:58:33

**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 ☒

US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:58:33

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 12:01
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:58:33

**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 ☒

US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:58:33

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 12:11
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3342088

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:58:33

Was Contact Attempted?

Yes ☒

No ☐

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

24 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3342088

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:58:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342088

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:58:33

Was Contact Attempted?

Yes ☒

No ☐

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

31 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3342088

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:58:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3342088

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:58:33

Was Contact Attempted?

Yes ☒

No ☐

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

8 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3342088

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:58:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342088

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:58:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 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	VISIT2

US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:33

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)	17 SEP 2020
Time of assessment (00:00-23:59)	13:41 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 13:41
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:58:33

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	

US3342088

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:58:33

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 SEP 2020

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

US3342088

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:58:33

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	17 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3342088

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:58:33

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 SAE NEW DX OF COLON CANCER

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? \_\_\_\_\_



US3342088

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:58:33

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	17 SEP 2020
Collection time ( <i>00:00-23:59</i> )	14:12 (24 HR)
Collection date and time (derived)	17 SEP 2020 14:12

US3342088

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:58:33

Collection date (dd MMM yyyy)			17 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:13	17 SEP 2020 14:13
Nasopharyngeal Swab 2	No		

US3342088

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:58:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342088

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:58:33

Was Contact Attempted?

Yes ☒

No ☐

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

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

VM LEFT ON 24SEP2020,  
25SEP2020, AND 28SEP2020

*If Contact Not Made, please provide Comments*

US3342088

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:58:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342088

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:58:33

Was Contact Attempted?

Yes ☒

No ☐

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

2 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3342088

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:58:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342088

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:58:33

Was Contact Attempted?

Yes ☒

No ☐

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

9 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3342088

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:58:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342088

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:58:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3342088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:33

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	14 OCT 2020
Time of assessment ( <i>00:00-23:59</i> )	13:13 (24 HR)
Vital Signs Date and Time (derived)	14 OCT 2020 13:13
Temperature ( <i>xxx.x</i> )	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	71 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3342088

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:58:33

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.*

US3342088

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:58:33

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	14 OCT 2020
Collection time ( <i>00:00-23:59</i> )	14:02 (24 HR)
Collection date and time (derived)	14 OCT 2020 14:02

US3342088

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:58:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

**TIMEPOINT**

DAY 64

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

No ☒

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

18 OCT 2020 08:23:07

Patient Cloud Open Date & Time

17 OCT 2020 00:01

Patient Cloud Close Date & Time

21 OCT 2020 23:59

US3342088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

**TIMEPOINT**

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 OCT 2020 21:58:27

Patient Cloud Open Date & Time

24 OCT 2020 00:01

Patient Cloud Close Date & Time

28 OCT 2020 23:59



US3342088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

**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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 OCT 2020 08:45:31

Patient Cloud Open Date & Time

31 OCT 2020 00:01

Patient Cloud Close Date & Time

04 NOV 2020 23:59

US3342088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

**TIMEPOINT**

DAY 92

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 NOV 2020 12:06:33

Patient Cloud Open Date & Time

14 NOV 2020 00:01

Patient Cloud Close Date & Time

18 NOV 2020 23:59

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 OCT 2020 23:59

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	21 OCT 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 OCT 2020 23:59

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 OCT 2020 00:01

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[Patient Cloud Close Date & Time](#)

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01 NOV 2020 23:59

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US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

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"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 2020 00:01

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[Patient Cloud Close Date & Time](#)

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08 NOV 2020 23:59

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US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

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 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"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 NOV 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 NOV 2020 23:59

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

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 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"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	18 NOV 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 NOV 2020 23:59

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	25 NOV 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 NOV 2020 23:59



US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

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 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"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 DEC 2020 00:01

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[Patient Cloud Close Date & Time](#)

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06 DEC 2020 23:59

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US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 DEC 2020 00:01

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[Patient Cloud Close Date & Time](#)

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13 DEC 2020 23:59

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US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	16 DEC 2020 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	20 DEC 2020 23:59
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US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

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 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"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	23 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 DEC 2020 23:59



US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

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 <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"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 DEC 2020 00:01

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[Patient Cloud Close Date & Time](#)

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03 JAN 2021 23:59

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US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

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[Patient Cloud Close Date & Time](#)

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10 JAN 2021 23:59

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US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

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 <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"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

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[Patient Cloud Close Date & Time](#)

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17 JAN 2021 23:59

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US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

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"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

20 JAN 2021 00:01

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[Patient Cloud Close Date & Time](#)

24 JAN 2021 23:59

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US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

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="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"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

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[Patient Cloud Close Date & Time](#)

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31 JAN 2021 23:59

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US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

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 <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"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

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[Patient Cloud Close Date & Time](#)

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07 FEB 2021 23:59

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US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

10 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

14 FEB 2021 23:59

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US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

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 <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"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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



US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

[Patient Cloud Close Date & Time](#)

28 FEB 2021 23:59

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

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[Patient Cloud Close Date & Time](#)

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07 MAR 2021 23:59

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US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

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

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 MAR 2021 00:01

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21 MAR 2021 23:59



US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

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[Patient Cloud Close Date & Time](#)

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28 MAR 2021 23:59

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US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

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[Patient Cloud Close Date & Time](#)

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04 APR 2021 23:59

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US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

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11 APR 2021 23:59

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US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

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"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

14 APR 2021 00:01

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[Patient Cloud Close Date & Time](#)

18 APR 2021 23:59

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US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

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

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

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[Patient Cloud Close Date & Time](#)

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25 APR 2021 23:59

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US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

**TIMEPOINT**

DAY 257

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

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

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

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

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

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

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

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

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

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[Patient Cloud Close Date & Time](#)

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02 MAY 2021 23:59

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US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

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"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

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[Patient Cloud Close Date & Time](#)

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09 MAY 2021 23:59

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US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

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

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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12 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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16 MAY 2021 23:59

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US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

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"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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19 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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23 MAY 2021 23:59

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US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

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"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

**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 ☐

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

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"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59



US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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16 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 JUN 2021 23:59

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US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	23 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 JUN 2021 23:59

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

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"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	04 JUL 2021 23:59

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

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[Patient Cloud Close Date & Time](#)

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11 JUL 2021 23:59

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US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

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"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

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[Patient Cloud Close Date & Time](#)

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18 JUL 2021 23:59

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US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

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"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

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[Patient Cloud Close Date & Time](#)

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25 JUL 2021 23:59

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US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

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"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

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[Patient Cloud Close Date & Time](#)

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01 AUG 2021 23:59

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US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

**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 ☐

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

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[Patient Cloud Close Date & Time](#)

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08 AUG 2021 23:59

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US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

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

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	11 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	15 AUG 2021 23:59
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US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

TIMEPOINT	DAY 369
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	18 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 AUG 2021 23:59

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

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="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"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	25 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 AUG 2021 23:59

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

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

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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



US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

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

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

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[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

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US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

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 <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"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

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"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	22 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 SEP 2021 23:59

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

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"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

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[Patient Cloud Close Date & Time](#)

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03 OCT 2021 23:59

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US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

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[Patient Cloud Close Date & Time](#)

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10 OCT 2021 23:59

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US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

**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 ☐  
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 ☐

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	13 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 OCT 2021 23:59

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	20 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 OCT 2021 23:59

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

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"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	27 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 OCT 2021 23:59



US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

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="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"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

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

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

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[Patient Cloud Close Date & Time](#)

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14 NOV 2021 23:59

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US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

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"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

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[Patient Cloud Close Date & Time](#)

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21 NOV 2021 23:59

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US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

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

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	24 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 NOV 2021 23:59



US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

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[Patient Cloud Close Date & Time](#)

05 DEC 2021 23:59

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US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

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"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

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[Patient Cloud Close Date & Time](#)

12 DEC 2021 23:59

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US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

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

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

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

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

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[Patient Cloud Close Date & Time](#)

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26 DEC 2021 23:59

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US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

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[Patient Cloud Close Date & Time](#)

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02 JAN 2022 23:59

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US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

**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 ☐

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

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[Patient Cloud Close Date & Time](#)

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09 JAN 2022 23:59

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US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

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

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

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

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

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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19 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 JAN 2022 23:59

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US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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26 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 JAN 2022 23:59

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US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

**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 ☐

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

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[Patient Cloud Close Date & Time](#)

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06 FEB 2022 23:59

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US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

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

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

09 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

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US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

**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 ☐

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59



US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

**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 ☐

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

27 FEB 2022 23:59

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

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 <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"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

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[Patient Cloud Close Date & Time](#)

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06 MAR 2022 23:59

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US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

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[Patient Cloud Close Date & Time](#)

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13 MAR 2022 23:59

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US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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16 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 MAR 2022 23:59

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US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

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[Patient Cloud Close Date & Time](#)

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27 MAR 2022 23:59

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US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

**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 ☐

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

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[Patient Cloud Close Date & Time](#)

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03 APR 2022 23:59

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US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

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"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

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[Patient Cloud Close Date & Time](#)

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10 APR 2022 23:59

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US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

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"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	13 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 APR 2022 23:59



US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

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

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

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[Patient Cloud Close Date & Time](#)

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24 APR 2022 23:59

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US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

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"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

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"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

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[Patient Cloud Close Date & Time](#)

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08 MAY 2022 23:59

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US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

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[Patient Cloud Close Date & Time](#)

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15 MAY 2022 23:59

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US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

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"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

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[Patient Cloud Close Date & Time](#)

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22 MAY 2022 23:59

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US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

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"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

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[Patient Cloud Close Date & Time](#)

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29 MAY 2022 23:59

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US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

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[Patient Cloud Close Date & Time](#)

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05 JUN 2022 23:59

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US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

**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 ☐

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	08 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 JUN 2022 23:59



US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

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="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"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

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 ☐

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	22 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 JUN 2022 23:59

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

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[Patient Cloud Close Date & Time](#)

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03 JUL 2022 23:59

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US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

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"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

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[Patient Cloud Close Date & Time](#)

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10 JUL 2022 23:59

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US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	13 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 JUL 2022 23:59

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

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

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

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

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	27 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 JUL 2022 23:59

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

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="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"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

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[Patient Cloud Close Date & Time](#)

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07 AUG 2022 23:59

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US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

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"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

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

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

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"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	28 AUG 2022 23:59
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US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

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="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"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

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[Patient Cloud Close Date & Time](#)

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04 SEP 2022 23:59

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US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

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[Patient Cloud Close Date & Time](#)

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11 SEP 2022 23:59

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US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

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

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

14 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

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US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

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"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

TIMEPOINT	DAY 775
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59



US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

TIMEPOINT	DAY 782
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	05 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	09 OCT 2022 23:59

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

US3342088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

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

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

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

US3342088

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:58:33

Was Contact Attempted?

Yes ☒

No ☐

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

9 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3342088

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:58:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



**US3342088**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:58:33**

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*

**US3342088**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:58:33**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3342088

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:58:33

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

**US3342088**

**Folder: Covid-19 Assessment (1)**

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

**Generated On: 26 Nov 2020 10:58:33**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3342088

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:58:33

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3342088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:33

AEID	USA-US203-2020-MRNA-1273-P30 1000001
Adverse event	STAGE III COLON CANCER
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)	15 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input 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	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
v6.020 DTW (1102)	309 of 1398

US3342088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:33

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

US3342088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:33

---

PATIENT DIAGNOSED WITH COLON CANCER ON 15SEP2020. NO STAGE WAS DETERMINED AND SURGERY HAS YET TO BE SCHEDULED. PATIENT SAYS CHEMOTHERAPY IS NOT EXPECTED AND SHOULD ONLY REQUIRE SURGERY. PATIENT UNDERWENT COLONIC TUMOR RESECTION WITH ILEOSTOMY ON 30SEP2020 (NOTED IN SOURCE 16OCT2020 PROGRESS NOTE). CON MEDICATION GIVEN FOR POST OPERATIVE PAIN MANAGEMENT (700MG ACETAMINOPHEN QID/PRN PO [ START 30SEP2020, END 03OCT2020 ] ). UPDATED CON MED LIST. DAO 05NOV2020.

---

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)	

---



US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:58:33

---

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

Yes ☒

No ☐

---

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

---

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:58:33

Name of Medication	INFLUENZA VACCINE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	WELLNESS
Dose per administration	1
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	INJECTION
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input checked="" type="radio"/>

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:58:33

	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"/>

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:58:33

Name of Medication	ACETAMINOPHEN
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	POST OPERATIVE PAIN (COLONIC TUMOR RESECTION)
Dose per administration	700
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input checked="" type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:58:33

	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"/>
<hr/>		
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		30 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy)		03 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
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"/>

US3342088

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 10:58:33

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3342088

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 10:58:33

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
30 SEP 2020	COLONIC TUMOR RESECTION	Adverse Event	
30 SEP 2020	ILEOSTOMY	Adverse Event	
16 OCT 2020	MRI POWER-PORT (FOR CHEMOTHERAPY) RIGHT SUBCLAVIAN.	Adverse Event	
31 AUG 2020	COLONOSCOPY	Diagnostic	
31 AUG 2020	EGD	Diagnostic	
22 SEP 2020	CT SCAN (CHEST, ABD, PELV) WITH CONTRAST	Diagnostic	

US3342088

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:58:33

Date of dosing discontinuation (dd MMM yyyy)

17 SEP 2020

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☒

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

AE #1



US3342088

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:58:33

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 ☐

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:58:33

SAEID	USA-US203-2020-MRNA-1273-P301000001
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:58:33

SAEID	USA-US203-2020-MRNA-1273-P301000001
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	18/SEP/2020 12:04
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

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:58:33

SAEID	USA-US203-2020-MRNA-1273-P301000001
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	12/OCT/2020 11:10
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

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 10:58:33

SAEID	USA-US203-2020-MRNA-1273-P301000001
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	15/OCT/2020 09:02
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

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 10:58:33

SAEID	USA-US203-2020-MRNA-1273-P301000001
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	06/NOV/2020 11:41
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

US3342088 (Prod: Tekton Research- Austin)

**US3342088**

**Form: Participant Creation**

**Generated On: 26 Nov 2020 10:58:33**

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3342088'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	17 Aug 2020 20:53:16



US3342088

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:58:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	John Luna (b) (4)	17 Aug 2020 22:05:50

US3342088

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered '17 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	17 Aug 2020 20:53:17

US3342088

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	John Luna (b) (4)	17 Aug 2020 22:05:50

**US3342088**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:58:33**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	17 Aug 2020 22:05:50

US3342088

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:58:33

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User entered (b) (6) 1970'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	17 Aug 2020 20:53:18

US3342088

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:58:33

[Age](#)

Audit	User	Time (GMT)
User entered '50'	John Luna (b) (4)	17 Aug 2020 22:06:04

US3342088

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:58:33

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	17 Aug 2020 22:06:04

US3342088

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:58:33

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '50'	System	17 Aug 2020 22:06:18



US3342088

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:58:33

[Sex](#)

Audit	User	Time (GMT)
User entered 'Female (F)'	John Luna (b) (4)	17 Aug 2020 22:06:04

US3342088

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:58:33

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	John Luna (b) (4)	17 Aug 2020 22:06:04

US3342088

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:58:33

White

Audit	User	Time (GMT)
User entered 'I'	John Luna (b) (4)	17 Aug 2020 22:06:04

US3342088

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:58:33

[Black](#)

Audit	User	Time (GMT)
User entered '0'	John Luna (b) (4)	17 Aug 2020 22:06:04

**US3342088**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:58:33**

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	John Luna (b) (4)	17 Aug 2020 22:06:04

US3342088

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:58:33

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	John Luna (b) (4)	17 Aug 2020 22:06:04

US3342088

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:58:33

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	John Luna (b) (4)	17 Aug 2020 22:06:04

US3342088

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:58:33

[Other](#)

Audit	User	Time (GMT)
User entered '0'	John Luna (b) (4)	17 Aug 2020 22:06:04



US3342088

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:58:33

If race is Other, specify

Audit	User	Time (GMT)
User entered empty.	John Luna (b) (4)	17 Aug 2020 22:06:04

**US3342088**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:58:33**

[Unknown](#)

Audit	User	Time (GMT)
User entered '0'	John Luna (b) (4)	17 Aug 2020 22:06:04

US3342088

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:58:33

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	John Luna (b) (4)	17 Aug 2020 22:06:04

US3342088

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:58:33

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '17 Aug 2020'	John Luna (b) (4)	17 Aug 2020 22:06:18

US3342088

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:58:33**

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	17 Aug 2020 22:06:18

US3342088

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered '2020'	System	17 Aug 2020 22:06:18

US3342088

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:58:33

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 2 (2)'	John Luna (b) (4)	17 Aug 2020 22:06:18

US3342088

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	John Luna (b) (4)	17 Aug 2020 22:06:18



US3342088

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:58:33

If No, indicate reason for screen fail

Audit	User	Time (GMT)
User entered empty.	John Luna (b) (4)	17 Aug 2020 22:06:18

US3342088

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:58:33

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	John Luna (b) (4)	17 Aug 2020 22:06:18

US3342088

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:58:33

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	John Luna (b) (4)	17 Aug 2020 22:06:18

US3342088

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:58:33

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	17 Aug 2020 20:53:17

US3342088

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:58:33

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Aug 2020 22:06:23

US3342088

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:58:33

Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	John Luna (b) (4)	17 Aug 2020 22:06:23

US3342088

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:58:33

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	John Luna (b) (4)	17 Aug 2020 22:09:13

US3342088

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:58:33

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis ascribed to specific agent, PT: Drug eruption, LLT: Allergic drug rash - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 12:30:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 12:30:41
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Sulfonamide allergy - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 07:17:14
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 07:17:14
Data point term sent to Coder	System	17 Aug 2020 22:10:24
User entered 'Sulfa Drug Allergy (Rash)'	John Luna (b) (4)	17 Aug 2020 22:09:46



US3342088

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered 'un UNK 1990'	John Luna (b) (4)	17 Aug 2020 22:09:46

US3342088

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:58:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	John Luna (b) (4)	17 Aug 2020 22:09:46

US3342088

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:58:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	John Luna (b) (4)	17 Aug 2020 22:09:46

**US3342088**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:58:33**

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

Audit	User	Time (GMT)
User entered empty.	John Luna (b) (4)	17 Aug 2020 22:09:46

US3342088

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:58:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	John Luna (b) (4)	17 Aug 2020 22:09:46

**US3342088**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:58:33**

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

Audit	User	Time (GMT)
User entered 'Jan 1990'	System	17 Aug 2020 22:09:46

**US3342088**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:58:33**

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

Audit	User	Time (GMT)
User entered '1990'	System	17 Aug 2020 22:09:46

US3342088

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 22:09:46



US3342088

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 22:09:46

US3342088

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:58:33

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Mononeuropathies, PT: Tarsal tunnel syndrome, LLT: Tarsal tunnel syndrome - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 07:03:17
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 07:03:17
Data point term sent to Coder	System	17 Aug 2020 22:10:24
User entered 'Tarsal Tunnel Syndrome Right Foot'	John Luna (b) (4)	17 Aug 2020 22:10:11

US3342088

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered 'un UNK 2018'	John Luna (b) (4)	17 Aug 2020 22:10:11

**US3342088**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:58:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	John Luna (b) (4)	17 Aug 2020 22:10:11

US3342088

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:58:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	John Luna (b) (4)	17 Aug 2020 22:10:11

US3342088

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered 'un UNK 2018'	John Luna (b) (4)	17 Aug 2020 22:10:11

US3342088

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:58:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	John Luna (b) (4)	17 Aug 2020 22:10:11

US3342088

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	17 Aug 2020 22:10:11



**US3342088**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:58:33**

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

Audit	User	Time (GMT)
User entered '2018'	System	17 Aug 2020 22:10:11

**US3342088**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:58:33**

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	17 Aug 2020 22:10:11

**US3342088**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:58:33**

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

Audit	User	Time (GMT)
User entered '2018'	System	17 Aug 2020 22:10:11

US3342088

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:58:33

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Peripheral nerve therapeutic procedures, PT: Tarsal tunnel decompression, LLT: Tarsal tunnel decompression - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 07:03:17
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 07:03:17
Data point term sent to Coder	System	17 Aug 2020 22:11:25
User entered 'Tarsal Tunnel Surgery Right Foot'	John Luna (b) (4)	17 Aug 2020 22:10:34

US3342088

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered 'un UNK 2018'	John Luna (b) (4)	17 Aug 2020 22:10:34

US3342088

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:58:33

Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	John Luna (b) (4)	17 Aug 2020 22:10:34

US3342088

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:58:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	John Luna (b) (4)	17 Aug 2020 22:10:34

US3342088

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered 'un UNK 2018'	John Luna (b) (4)	17 Aug 2020 22:10:34



US3342088

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:58:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	John Luna (b) (4)	17 Aug 2020 22:10:34

**US3342088**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:58:33**

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	17 Aug 2020 22:10:34

**US3342088**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:58:33**

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

Audit	User	Time (GMT)
User entered '2018'	System	17 Aug 2020 22:10:34

US3342088

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	17 Aug 2020 22:10:34

**US3342088**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:58:33**

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

Audit	User	Time (GMT)
User entered '2018'	System	17 Aug 2020 22:10:34

US3342088

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:58:33

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries by physical agents, HLT: Thermal burns, PT: Thermal burn, LLT: Burn of unspecified degree of unspecified site of upper limb - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 09:51:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 09:51:31
Data point term sent to Coder	System	17 Aug 2020 22:41:01
User entered 'Left Arm Minor Burn'	John Luna (b) (4)	17 Aug 2020 22:40:37

US3342088

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered '12 Aug 2020'	John Luna (b) (4)	17 Aug 2020 22:40:37

US3342088

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:58:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	John Luna (b) (4)	17 Aug 2020 22:40:37



US3342088

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:58:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	John Luna (b) (4)	17 Aug 2020 22:40:37

**US3342088**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:58:33**

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

Audit	User	Time (GMT)
User entered empty.	John Luna (b) (4)	17 Aug 2020 22:40:37

US3342088

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:58:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	John Luna (b) (4)	17 Aug 2020 22:40:37

**US3342088**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:58:33**

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	17 Aug 2020 22:40:37

**US3342088**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:58:33**

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

Audit	User	Time (GMT)
User entered '2020'	System	17 Aug 2020 22:40:37

US3342088

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 22:40:37

**US3342088**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:58:33**

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

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 22:40:37

US3342088

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	John Luna (b) (4)	17 Aug 2020 22:12:15



US3342088

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '17 Aug 2020'	John Luna (b) (4)	17 Aug 2020 22:12:15

US3342088

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered '15:31'	John Luna (b) (4)	17 Aug 2020 22:12:15

US3342088

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered '17 Aug 2020 15:31'	System	17 Aug 2020 22:12:15

US3342088

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered '165.0' cm	John Luna (b) (4)	17 Aug 2020 22:12:15
DataPoint set to visible.	System	17 Aug 2020 22:06:23

US3342088

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered '84.5' kg	John Luna	(b) (4) 17 Aug 2020 22:12:15
DataPoint set to visible.	System	17 Aug 2020 22:06:23

**US3342088**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:58:33**

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

Audit	User	Time (GMT)
Amendment Manager: User entered '31.03765'	System	17 Sep 2020 00:00:59
User entered '31.0'	System	17 Aug 2020 22:12:15
DataPoint set to visible.	System	17 Aug 2020 22:06:23

**US3342088**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:58:33**

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	17 Aug 2020 22:12:15
DataPoint set to visible.	System	17 Aug 2020 22:06:23

US3342088

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:33

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	John Luna (b) (4)	25 Aug 2020 17:42:52
User entered '98.3' F	John Luna (b) (4)	17 Aug 2020 22:12:15



**US3342088**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:58:33**

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	John Luna (b) (4)	25 Aug 2020 17:42:52
User entered 'Oral (Oral)'	John Luna (b) (4)	17 Aug 2020 22:12:15

US3342088

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:33

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	John Luna (b) (4)	17 Aug 2020 22:12:15

US3342088

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	John Luna (b) (4)	25 Aug 2020 17:42:52
User entered '59'	John Luna (b) (4)	17 Aug 2020 22:12:15

**US3342088**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:58:33**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	17 Aug 2020 22:12:15

US3342088

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	John Luna (b) (4)	25 Aug 2020 17:42:52
User entered '12'	John Luna (b) (4)	17 Aug 2020 22:12:15

US3342088

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	17 Aug 2020 22:12:15

US3342088

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	John Luna (b) (4)	25 Aug 2020 17:42:52
User entered '116'	John Luna (b) (4)	17 Aug 2020 22:12:15

US3342088

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Aug 2020 22:12:15



US3342088

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	John Luna (b) (4)	25 Aug 2020 17:42:52
User entered '76'	John Luna (b) (4)	17 Aug 2020 22:12:15

US3342088

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:33

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Aug 2020 22:12:15

US3342088

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:58:33

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	John Luna (b) (4)	17 Aug 2020 22:12:23

US3342088

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:58:33

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '17 Aug 2020'	John Luna (b) (4)	17 Aug 2020 22:12:23

US3342088

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:58:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '17 Aug 2020'	John Luna (b) (4)	17 Aug 2020 22:12:41

US3342088

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:58:33

Is the participant of childbearing potential?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	John Luna (b) (4)	17 Aug 2020 22:12:41

US3342088

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:58:33

[If No, what is the reason?](#)

Audit	User	Time (GMT)
User entered empty.	John Luna (b) (4)	17 Aug 2020 22:12:41

US3342088

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:58:33

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
User entered empty.	John Luna (b) (4)	17 Aug 2020 22:12:41



US3342088

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:58:33

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	John Luna (b) (4)	17 Aug 2020 22:12:41

US3342088

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:58:33

Date of surgery unknown

Audit	User	Time (GMT)
User entered '0'	John Luna (b) (4)	17 Aug 2020 22:12:41

US3342088

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:58:33

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	John Luna (b) (4)	17 Aug 2020 22:12:41

US3342088

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:58:33

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
User entered '0'	John Luna (b) (4)	17 Aug 2020 22:12:41

US3342088

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:58:33

Was the pregnancy test performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	John Luna (b) (4)	17 Aug 2020 22:13:59

US3342088

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:58:33

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '17 Aug 2020'	John Luna (b) (4)	17 Aug 2020 22:13:59

US3342088

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:58:33

[Test performed](#)

Audit	User	Time (GMT)
User entered 'Urine (URINE)'	John Luna (b) (4)	17 Aug 2020 22:13:59

US3342088

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:58:33

[Result](#)

Audit	User	Time (GMT)
User entered 'Negative (NEGATIVE)'	John Luna (b) (4)	17 Aug 2020 22:13:59



US3342088

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:58:33

Was FSH sample collected?

Audit	User	Time (GMT)
User closed query 'Per CDM: Was FSH sample collected is recorded as "No", however collection date and time is recorded. Please refer to eCCGs and update.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 06:48:54
Query 'Per CDM: Was FSH sample collected is recorded as "No", however collection date and time is recorded. Please refer to eCCGs and update.'	John Luna (b) (4)	09 Sep 2020 23:40:34
answered with 'data updated' (Site from DM).		
User opened query 'Per CDM: Was FSH sample collected is recorded as "No", however collection date and time is recorded. Please refer to eCCGs and update.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 09:16:51
User entered 'No (N)'	John Luna (b) (4)	17 Aug 2020 22:13:59

**US3342088**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 10:58:33**

[Collection date](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	John Luna (b) (4)	09 Sep 2020 23:40:44
User entered '17 Aug 2020'	John Luna (b) (4)	17 Aug 2020 22:13:59

**US3342088**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 10:58:33**

[Collection time](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	John Luna (b) (4)	09 Sep 2020 23:40:44
User entered '16:12'	John Luna (b) (4)	17 Aug 2020 22:13:59

**US3342088**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 10:58:33**

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

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 23:40:44
User entered '17 Aug 2020 16:12'	System	17 Aug 2020 22:13:59

US3342088

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered 'No (N)'	John Luna (b) (4)	17 Aug 2020 22:14:58

US3342088

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered 'No (N)'	John Luna (b) (4)	17 Aug 2020 22:14:58

US3342088

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:58:33

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
User entered 'No (N)'	John Luna (b) (4)	17 Aug 2020 22:14:58

US3342088

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:58:33

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
User entered 'No (N)'	John Luna (b) (4)	17 Aug 2020 22:14:58



US3342088

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered 'No (N)'	John Luna (b) (4)	17 Aug 2020 22:14:58

US3342088

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:58:33

**Transportation and delivery services** (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
User entered 'No (N)'	John Luna (b) (4)	17 Aug 2020 22:14:58

US3342088

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:58:33

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
User entered 'No (N)'	John Luna (b) (4)	17 Aug 2020 22:14:58

US3342088

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:58:33

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
User entered 'No (N)'	John Luna (b) (4)	17 Aug 2020 22:14:58

US3342088

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:58:33

**Hospitality and Tourism Workers** (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
User entered 'No (N)'	John Luna (b) (4)	17 Aug 2020 22:14:58

US3342088

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:58:33

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	John Luna (b) (4)	17 Aug 2020 22:14:58

US3342088

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:58:33

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
User entered 'No (N)'	John Luna (b) (4)	17 Aug 2020 22:14:58

US3342088

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:58:33

[Other](#)

Audit	User	Time (GMT)
User entered 'No (N)'	John Luna (b) (4)	17 Aug 2020 22:14:58



US3342088

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:58:33

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	John Luna (b) (4)	17 Aug 2020 22:14:58

US3342088

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:58:33

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	John Luna (b) (4)	17 Aug 2020 22:14:58

US3342088

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered '0'	John Luna (b) (4)	17 Aug 2020 22:14:58

US3342088

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:58:33

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
User entered '1'	John Luna (b) (4)	17 Aug 2020 22:14:58

US3342088

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:58:33

**Resides in high density housing** (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
User entered '0'	John Luna (b) (4)	17 Aug 2020 22:14:58

US3342088

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:58:33

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
User entered '0'	John Luna (b) (4)	17 Aug 2020 22:14:58

US3342088

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered '0'	John Luna (b) (4)	17 Aug 2020 22:14:58

US3342088

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:58:33

[Other](#)

Audit	User	Time (GMT)
User entered '0'	John Luna (b) (4)	17 Aug 2020 22:14:58



US3342088

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:58:33

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	John Luna (b) (4)	17 Aug 2020 22:14:58

US3342088

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:58:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	John Luna (b) (4)	17 Aug 2020 22:15:25

US3342088

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered '17 Aug 2020'	John Luna (b) (4)	17 Aug 2020 22:15:25

US3342088

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	John Luna (b) (4)	17 Aug 2020 22:15:25

**US3342088**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:58:33**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	17 Aug 2020 22:15:25

US3342088

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered '17 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	17 Aug 2020 21:41:17

US3342088

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:58:33

What was the participant's randomization number?

Audit	User	Time (GMT)
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 05:09:46
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:09:46
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	17 Aug 2020 21:41:17
User entered '105305' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	17 Aug 2020 21:41:17

US3342088

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	17 Aug 2020 21:41:17



US3342088

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:58:33

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
User entered 'No (N)'	John Luna (b) (4)	17 Aug 2020 22:07:00

US3342088

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:58:33

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
User entered 'No (N)'	John Luna (b) (4)	17 Aug 2020 22:07:00

US3342088

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered 'No (N)'	John Luna (b) (4)	17 Aug 2020 22:07:00

US3342088

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:58:33

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	John Luna (b) (4)	17 Aug 2020 22:07:00

US3342088

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:58:33

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	John Luna (b) (4)	17 Aug 2020 22:07:00

**US3342088**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 26 Nov 2020 10:58:33**

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

Audit	User	Time (GMT)
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:23:19
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:45:04

US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:58:33

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	John Luna (b) (4)	25 Aug 2020 17:42:24
User entered '165.0' cm	John Luna (b) (4)	17 Aug 2020 22:17:17

US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:58:33

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	John Luna (b) (4)	25 Aug 2020 17:42:24
User entered '84.5' kg	John Luna (b) (4)	17 Aug 2020 22:17:17



US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:58:33

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	John Luna (b) (4)	25 Aug 2020 17:42:24
User entered '165.0' cm	John Luna (b) (4)	17 Aug 2020 22:17:17

US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:58:33

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	John Luna (b) (4)	25 Aug 2020 17:42:24
User entered '84.5' kg	John Luna (b) (4)	17 Aug 2020 22:17:17

US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:33

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	John Luna (b) (4)	17 Aug 2020 22:17:17

US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:33

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	John Luna (b) (4)	17 Aug 2020 22:17:17

US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '17 Aug 2020'	John Luna (b) (4)	17 Aug 2020 22:17:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered '15:31'	John Luna (b) (4)	17 Aug 2020 22:17:17

**US3342088**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:58:33**

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

Audit	User	Time (GMT)
User entered '17 Aug 2020 15:31'	System	17 Aug 2020 22:17:17

US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:33

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.3' F	John Luna (b) (4)	17 Aug 2020 22:17:17



US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:33

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	John Luna (b) (4)	17 Aug 2020 22:17:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:33

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	John Luna (b) (4)	17 Aug 2020 22:17:17

US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '59'	John Luna (b) (4)	17 Aug 2020 22:17:17

US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:33

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	17 Aug 2020 22:17:17

US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered '12'	John Luna (b) (4)	17 Aug 2020 22:17:17

US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	17 Aug 2020 22:17:17

US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '116'	John Luna (b) (4)	17 Aug 2020 22:17:17

US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Aug 2020 22:17:17



US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '76'	John Luna (b) (4)	17 Aug 2020 22:17:17

US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:33

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Aug 2020 22:17:17

US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:58:33

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	John Luna (b) (4)	25 Aug 2020 17:42:24
User entered '165.0' cm	John Luna (b) (4)	17 Aug 2020 22:17:17

US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:58:33

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	John Luna (b) (4)	25 Aug 2020 17:42:24
User entered '84.5' kg	John Luna (b) (4)	17 Aug 2020 22:17:17

US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:58:33

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	John Luna (b) (4)	17 Aug 2020 22:17:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:58:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Aug 2020 22:39:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Aug 2020 22:39:09
User entered 'Yes (Y)' reason for change: Data Entry Error	John Luna (b) (4)	17 Aug 2020 22:39:09
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Aug 2020 22:17:17
User entered empty.	John Luna (b) (4)	17 Aug 2020 22:17:17

US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:58:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '17 Aug 2020' reason for change: Data Entry Error	John Luna (b) (4)	17 Aug 2020 22:39:09
User entered empty.	John Luna (b) (4)	17 Aug 2020 22:17:17

US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	20 Aug 2020 11:47:42
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		17 Aug 2020 22:39:09
User entered '17:27' reason for change: Data Entry Error	John Luna (b) (4)	17 Aug 2020 22:39:09
User entered empty.	John Luna (b) (4)	17 Aug 2020 22:17:17



**US3342088**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:58:33**

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

Audit	User	Time (GMT)
User entered '17 Aug 2020 17:27'	System	17 Aug 2020 22:39:09
User entered empty.	System	17 Aug 2020 22:17:17

US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:58:33

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.2' F reason for change: Data Entry Error	John Luna (b) (4)	17 Aug 2020 22:39:09
User entered empty.	John Luna (b) (4)	17 Aug 2020 22:17:17

US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:58:33

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)' reason for change: Data Entry Error	John Luna (b) (4)	17 Aug 2020 22:39:09
User entered empty.	John Luna (b) (4)	17 Aug 2020 22:17:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:58:33

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	John Luna (b) (4)	17 Aug 2020 22:17:17

US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:58:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '56' reason for change: Data Entry Error	John Luna (b) (4)	17 Aug 2020 22:39:09
User entered empty.	John Luna (b) (4)	17 Aug 2020 22:17:17

**US3342088**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:58:33**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	17 Aug 2020 22:39:09
User entered empty.	System	17 Aug 2020 22:17:17

US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered '12' reason for change: Data Entry Error	John Luna (b) (4)	17 Aug 2020 22:39:09
User entered empty.	John Luna (b) (4)	17 Aug 2020 22:17:17

US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:58:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	17 Aug 2020 22:39:09
User entered empty.	System	17 Aug 2020 22:17:17



US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:58:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '122' reason for change: Data Entry Error	John Luna (b) (4)	17 Aug 2020 22:39:09
User entered empty.	John Luna (b) (4)	17 Aug 2020 22:17:17

US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:58:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Aug 2020 22:39:09
User entered empty.	System	17 Aug 2020 22:17:17

US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:58:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '81' reason for change: Data Entry Error	John Luna (b) (4)	17 Aug 2020 22:39:09
User entered empty.	John Luna (b) (4)	17 Aug 2020 22:17:17

US3342088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:58:33

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Aug 2020 22:39:09
User entered empty.	System	17 Aug 2020 22:17:17

US3342088

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:58:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	John Luna (b) (4)	25 Aug 2020 17:42:11
User entered 'Yes (Y)'	John Luna (b) (4)	17 Aug 2020 22:15:31

US3342088

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:58:33

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	John Luna (b) (4)	25 Aug 2020 17:42:11
User entered '17 Aug 2020'	John Luna (b) (4)	17 Aug 2020 22:15:31

US3342088

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:58:33

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Thank you. Per version 1.0 of the CCGs data was entered correctly, however; to eliminate duplicate data the newest version 2.0 of the CCGs will have updated data entry guidelines. Per Sponsor, If Screening and Visit 1 Day 1 are done on the same day, please enter Pregnancy Test (if applicable) at Screening, and select No at Visit 1 Day 1 Pregnancy Test. Thank you.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 14:24:02
Query 'Per CDM: Thank you. Per version 1.0 of the CCGs data was entered correctly, however; to eliminate duplicate data the newest version 2.0 of the CCGs will have updated data entry guidelines. Per Sponsor, If Screening and Visit 1 Day 1 are done on the same day, please enter Pregnancy Test (if applicable) at Screening, and select No at Visit 1 Day 1 Pregnancy Test. Thank you.' answered with 'Pregnancy test listed in screening visit only.' (Site from DM).	Ethan Shotton (b) (4) (b) (4)	05 Nov 2020 22:39:42
User entered 'No (N)' reason for change: Data Entry Error	Ethan Shotton (b) (4) (b) (4)	05 Nov 2020 22:39:02
User opened query 'Per CDM: Thank you. Per version 1.0 of the CCGs data was entered correctly, however; to eliminate duplicate data the newest version 2.0 of the CCGs will have updated data entry guidelines. Per Sponsor, If Screening and Visit 1 Day 1 are done on the same day, please enter Pregnancy Test (if applicable) at Screening, and select No at Visit 1 Day 1 Pregnancy Test. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 19:57:23
User closed query 'Per CDM: Thank you for your answer. However, please be aware that Screening and Visit 1 Day 1 "Dates" are the same which means that Visit 1 Day 1 "Pregnancy Test" form is duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No". Thank you!' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 19:57:16

US3342088

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:58:33

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Query 'Per CDM: Thank you for your answer. However, please be aware that Screening and Visit 1 Day 1 "Dates" are the same which means that Visit 1 Day 1 "Pregnancy Test" form is duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No". Thank you!' answered with 'Per CRF guidelines, both screening and baseline pregnancy test CRFs are to be completed if dosed same day as screening' (Site from DM).	Eileen Euperio (b) (4)	25 Sep 2020 14:42:29
User opened query 'Per CDM: Thank you for your answer. However, please be aware that Screening and Visit 1 Day 1 "Dates" are the same which means that Visit 1 Day 1 "Pregnancy Test" form is duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No". Thank you!' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 08:09:56
User closed query 'Per CDM: Thank you for your answer. However, please be aware that Screening and Visit 1 Day 1 "Dates" are the same which means that Visit 1 Day 1 "Pregnancy Test" form is duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No". Thank you!' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 19:58:43
Query 'Per CDM: Thank you for your answer. However, please be aware that Screening and Visit 1 Day 1 "Dates" are the same which means that Visit 1 Day 1 "Pregnancy Test" form is duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No". Thank you!' answered with 'Understood. However, per the current eCRF Completion Guidelines, pages 15 and 16, under "DATA REQUIREMENTS", the information required to be input is listed as "Pregnancy Test (if applicable)" in the Screening Visit folder and again information is required to be input listed as "Pregnancy Test (if applicable)" in the Visit 1 Day 1 folder.' (Site from DM).	Darrell O'Brien (b) (4)	11 Sep 2020 23:11:46



US3342088

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:58:33

Was the pregnancy test performed?

Audit	User	Time (GMT)
User opened query 'Per CDM: Thank you for your answer. However, please be aware that Screening and Visit 1 Day 1 "Dates" are the same which means that Visit 1 Day 1 "Pregnancy Test" form is duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No". Thank you!' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 07:46:51
User closed query 'Per CDM: This data seems to be a duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No" and keeping the eCRF blank at Visit 1 Day 1.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 07:46:51
Query 'Per CDM: This data seems to be a duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No" and keeping the eCRF blank at Visit 1 Day 1.' answered with 'Per eCRF guide, data entered on both pages.' (Site from DM).	John Luna (b) (4)	09 Sep 2020 23:40:21
User opened query 'Per CDM: This data seems to be a duplicate of the pregnancy test performed at screening visit. Kindly consider only keeping one record (at screening) and updating this assessment as "No" and keeping the eCRF blank at Visit 1 Day 1.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 09:17:01
User entered 'Yes (Y)'	John Luna (b) (4)	17 Aug 2020 22:15:57

US3342088

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:58:33

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Ethan Shotton (b) (4)	05 Nov 2020 22:39:02
User entered '17 Aug 2020'	John Luna (b) (4)	17 Aug 2020 22:15:57

US3342088

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:58:33

[Test performed](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Ethan Shotton (b) (4)	05 Nov 2020 22:39:02
User entered 'Urine (URINE)'	John Luna (b) (4)	17 Aug 2020 22:15:57

US3342088

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:58:33

[Result](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Ethan Shotton (b) (4)	05 Nov 2020 22:39:02
User entered 'Negative (NEGATIVE)'	John Luna (b) (4)	17 Aug 2020 22:15:57

US3342088

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:58:33

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Ethan Shotton (b) (4)	05 Nov 2020 22:39:02
User entered 'No (N)'	John Luna (b) (4)	17 Aug 2020 22:15:57

**US3342088**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 10:58:33**

[Collection date](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Ethan Shotton (b) (4)	05 Nov 2020 22:39:02
User entered '17 Aug 2020'	John Luna (b) (4)	17 Aug 2020 22:15:57

US3342088

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:58:33

[Collection time](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Ethan Shotton (b) (4)	05 Nov 2020 22:39:02
User entered '16:12'	John Luna (b) (4)	17 Aug 2020 22:15:57

**US3342088**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 26 Nov 2020 10:58:33**

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

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 22:39:02
User entered '17 Aug 2020 16:12'	System	17 Aug 2020 22:15:57



US3342088

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:58:33

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	John Luna (b) (4)	17 Aug 2020 22:07:28

US3342088

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:58:33

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	John Luna (b) (4)	17 Aug 2020 22:07:28

US3342088

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered empty.	John Luna (b) (4)	17 Aug 2020 22:07:28

US3342088

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:58:33

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	17 Aug 2020 22:07:28

US3342088

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:58:33

What was the treatment date? (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '17 Aug 2020'	John Luna (b) (4)	17 Aug 2020 22:07:28

US3342088

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered '16:57'	John Luna (b) (4)	17 Aug 2020 22:07:28

US3342088

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered '17 Aug 2020 16:57'	System	17 Aug 2020 22:07:28

US3342088

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:58:33

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Right Arm (RIGHT ARM)'	John Luna (b) (4)	17 Aug 2020 22:07:28



US3342088

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	17 Aug 2020 22:07:28

US3342088

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:58:33

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	17 Aug 2020 22:07:28

US3342088

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:58:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	19 Aug 2020 22:31:55

US3342088

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:58:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '17 Aug 2020'	Eileen Euperio (b) (4) (b) (4)	19 Aug 2020 22:31:55

US3342088

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:58:33

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '16:33'	Eileen Euperio (b) (4) (b) (4)	19 Aug 2020 22:31:55

US3342088

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered '17 Aug 2020 16:33'	System	19 Aug 2020 22:31:55

US3342088

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:58:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '17 Aug 2020'	Eileen Euperio (b) (4) (b) (4)	19 Aug 2020 22:32:04

US3342088

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:58:33

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Eileen Euperio (b) (4) (b) (4)	19 Aug 2020 22:32:04



US3342088

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:58:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	19 Aug 2020 22:32:04

US3342088

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:58:33

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '16:35'	Eileen Euperio (b) (4) (b) (4)	19 Aug 2020 22:32:04

US3342088

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered '17 Aug 2020 16:35'	System	19 Aug 2020 22:32:04

US3342088

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:58:33

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Eileen Euperio (b) (4) (b) (4)	19 Aug 2020 22:32:04

US3342088

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:58:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	19 Aug 2020 22:32:04

US3342088

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:58:33

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	19 Aug 2020 22:32:04

**US3342088**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 10:58:33**

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 22:32:04

US3342088

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:58:33

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	John Luna (b) (4)	17 Aug 2020 22:16:07



**US3342088**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:58:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 22:16:07

**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 22:07:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:58:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T17:29:09', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'a781a35d-0da9-47ba-b160-58d7e3df15c1'	System	17 Aug 2020 22:29:28
User entered 'Yes (Y)'	System	17 Aug 2020 22:29:28

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:58:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T17:29:16', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'a781a35d-0da9-47ba-b160-58d7e3df15c1'	System	17 Aug 2020 22:29:28
User entered '98.2'	System	17 Aug 2020 22:29:28

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T17:29:21', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'a781a35d-0da9-47ba-b160-58d7e3df15c1'	System	17 Aug 2020 22:29:28
User entered 'No (N)'	System	17 Aug 2020 22:29:28

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:58:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T17:29:26', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'a781a35d-0da9-47ba-b160-58d7e3df15c1'	System	17 Aug 2020 22:29:28
User entered '17 Aug 2020 17:29'	System	17 Aug 2020 22:29:28

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:58:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 17:17'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:58:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 19:47'	System	17 Aug 2020 22:07:28



**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 22:07:28
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:58:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T21:32:29', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'cc9c8d2f-2290-4407-9556-5a42efb398ad'	System	18 Aug 2020 02:32:47
User entered 'Yes (Y)'	System	18 Aug 2020 02:32:47

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:58:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T21:32:35', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'cc9c8d2f-2290-4407-9556-5a42efb398ad'	System	18 Aug 2020 02:32:47
User entered '98.2'	System	18 Aug 2020 02:32:47

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T21:32:39', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'cc9c8d2f-2290-4407-9556-5a42efb398ad'	System	18 Aug 2020 02:32:47
User entered 'No (N)'	System	18 Aug 2020 02:32:47

**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:58:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T21:32:44', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'cc9c8d2f-2290-4407-9556-5a42efb398ad'	System	18 Aug 2020 02:32:47
User entered '17 Aug 2020 21:32'	System	18 Aug 2020 02:32:47

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:58:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 20:42'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:58:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 22:07:28

**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 22:07:28
User entered 'Day 2'	System	17 Aug 2020 22:07:28



US3342088

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:58:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-18T12:02:13', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '8592fe6c-6cf6-4c50-8be6-b71eb18adddf'	System	18 Aug 2020 17:02:41
User entered 'Yes (Y)'	System	18 Aug 2020 17:02:41

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:58:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-18T12:02:18', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '8592fe6c-6cf6-4c50-8be6-b71eb18adddf'	System	18 Aug 2020 17:02:41
User entered '98.2'	System	18 Aug 2020 17:02:41

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-18T12:02:21', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '8592fe6c-6cf6-4c50-8be6-b71eb18adddf'	System	18 Aug 2020 17:02:41
User entered 'No (N)'	System	18 Aug 2020 17:02:41

**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:58:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-18T12:02:24', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '8592fe6c-6cf6-4c50-8be6-b71eb18adddf'	System	18 Aug 2020 17:02:41
User entered '18 Aug 2020 12:02'	System	18 Aug 2020 17:02:41

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:58:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:58:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 22:07:28

**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 22:07:28
User entered 'Day 3'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:58:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-19T12:37:36', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '28a0cb03-c65c-46a3-ba23-ce923feb5c13'	System	19 Aug 2020 17:37:52
User entered 'Yes (Y)'	System	19 Aug 2020 17:37:52



US3342088

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:58:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-19T12:37:41', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '28a0cb03-c65c-46a3-ba23-ce923feb5c13'	System	19 Aug 2020 17:37:52
User entered '97.2'	System	19 Aug 2020 17:37:52

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-19T12:37:45', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '28a0cb03-c65c-46a3-ba23-ce923feb5c13'	System	19 Aug 2020 17:37:52
User entered 'No (N)'	System	19 Aug 2020 17:37:52

**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:58:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-19T12:37:50', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '28a0cb03-c65c-46a3-ba23-ce923feb5c13'	System	19 Aug 2020 17:37:52
User entered '19 Aug 2020 12:37'	System	19 Aug 2020 17:37:52

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:58:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:58:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 22:07:28

**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 22:07:28
User entered 'Day 4'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:58:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-20T12:38:37', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '5f8d09f0-3f65-49ae-ab96-50b95651cb12'	System	20 Aug 2020 17:38:54
User entered 'Yes (Y)'	System	20 Aug 2020 17:38:54

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:58:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-20T12:38:44', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '5f8d09f0-3f65-49ae-ab96-50b95651cb12'	System	20 Aug 2020 17:38:54
User entered '98.2'	System	20 Aug 2020 17:38:54



US3342088

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-20T12:38:47', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '5f8d09f0-3f65-49ae-ab96-50b95651cb12'	System	20 Aug 2020 17:38:54
User entered 'No (N)'	System	20 Aug 2020 17:38:54

**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:58:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-20T12:38:51', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '5f8d09f0-3f65-49ae-ab96-50b95651cb12'	System	20 Aug 2020 17:38:54
User entered '20 Aug 2020 12:38'	System	20 Aug 2020 17:38:54

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:58:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:58:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 22:07:28

**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 22:07:28
User entered 'Day 5'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:58:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-21T12:01:39', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'cbf0b95a-9327-425d-9987-2e792617295e'	System	21 Aug 2020 17:02:05
User entered 'Yes (Y)'	System	21 Aug 2020 17:02:05

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:58:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-21T12:01:47', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'cbf0b95a-9327-425d-9987-2e792617295e'	System	21 Aug 2020 17:02:05
User entered '97.4'	System	21 Aug 2020 17:02:05

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-21T12:01:50', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'cbf0b95a-9327-425d-9987-2e792617295e'	System	21 Aug 2020 17:02:05
User entered 'No (N)'	System	21 Aug 2020 17:02:05



**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:58:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-21T12:01:54', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'cbf0b95a-9327-425d-9987-2e792617295e'	System	21 Aug 2020 17:02:05
User entered '21 Aug 2020 12:01'	System	21 Aug 2020 17:02:05

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:58:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:58:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:58:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 22:07:28
User entered 'Day 6'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:58:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-22T12:01:12', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '9cc8c185-0bca-4c73-ae1c-1c49795899b9'	System	22 Aug 2020 17:01:29
User entered 'Yes (Y)'	System	22 Aug 2020 17:01:29

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:58:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-22T12:01:18', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '9cc8c185-0bca-4c73-ae1c-1c49795899b9'	System	22 Aug 2020 17:01:29
User entered '98.4'	System	22 Aug 2020 17:01:29

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-22T12:01:23', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '9cc8c185-0bca-4c73-ae1c-1c49795899b9'	System	22 Aug 2020 17:01:29
User entered 'No (N)'	System	22 Aug 2020 17:01:29

**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:58:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-22T12:01:26', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '9cc8c185-0bca-4c73-ae1c-1c49795899b9'	System	22 Aug 2020 17:01:29
User entered '22 Aug 2020 12:01'	System	22 Aug 2020 17:01:29



US3342088

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:58:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:58:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 22:07:28

**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 22:07:28
User entered 'Day 7'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:58:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-23T12:10:59', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '1a6551a1-e750-4515-9dc2-bb931ede3fe3'	System	23 Aug 2020 17:11:10
User entered 'Yes (Y)'	System	23 Aug 2020 17:11:10

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:58:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-23T12:11:03', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '1a6551a1-e750-4515-9dc2-bb931ede3fe3'	System	23 Aug 2020 17:11:10
User entered '98.2'	System	23 Aug 2020 17:11:10

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-23T12:11:05', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '1a6551a1-e750-4515-9dc2-bb931ede3fe3'	System	23 Aug 2020 17:11:10
User entered 'No (N)'	System	23 Aug 2020 17:11:10

**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:58:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-23T12:11:08', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '1a6551a1-e750-4515-9dc2-bb931ede3fe3'	System	23 Aug 2020 17:11:10
User entered '23 Aug 2020 12:11'	System	23 Aug 2020 17:11:10

US3342088

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:58:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 22:07:28



US3342088

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:58:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 22:07:28

**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 22:07:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:58:33

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T17:29:49', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'b56cca59-ac60-4027-a1c6-a88588f87cbd'	System	17 Aug 2020 22:30:07
User entered 'None (1)'	System	17 Aug 2020 22:30:07

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:58:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T17:29:53', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'b56cca59-ac60-4027-a1c6-a88588f87cbd'	System	17 Aug 2020 22:30:07
User entered 'No (N)'	System	17 Aug 2020 22:30:07

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T17:29:56', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'b56cca59-ac60-4027-a1c6-a88588f87cbd'	System	17 Aug 2020 22:30:07
User entered 'No (N)'	System	17 Aug 2020 22:30:07

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:58:33

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T17:30:00', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'b56cca59-ac60-4027-a1c6-a88588f87cbd'	System	17 Aug 2020 22:30:07
User entered 'None (1)'	System	17 Aug 2020 22:30:07

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:58:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T17:30:03', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'b56cca59-ac60-4027-a1c6-a88588f87cbd'	System	17 Aug 2020 22:30:07
User entered '17 Aug 2020 17:30'	System	17 Aug 2020 22:30:07

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:58:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 17:17'	System	17 Aug 2020 22:07:28



**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:58:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 19:47'	System	17 Aug 2020 22:07:28

**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 22:07:28
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:58:33

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T21:32:48', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '31b29293-eeae-48de-8bb5-c1ea102f2a47'	System	18 Aug 2020 02:33:02
User entered 'None (1)'	System	18 Aug 2020 02:33:02

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:58:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T21:32:51', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '31b29293-eeae-48de-8bb5-c1ea102f2a47'	System	18 Aug 2020 02:33:02
User entered 'No (N)'	System	18 Aug 2020 02:33:02

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T21:32:54', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '31b29293-eeae-48de-8bb5-c1ea102f2a47'	System	18 Aug 2020 02:33:02
User entered 'No (N)'	System	18 Aug 2020 02:33:02

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:58:33

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T21:32:57', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '31b29293-eeae-48de-8bb5-c1ea102f2a47'	System	18 Aug 2020 02:33:02
User entered 'None (1)'	System	18 Aug 2020 02:33:02

**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:58:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T21:33:00', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '31b29293-eeae-48de-8bb5-c1ea102f2a47'	System	18 Aug 2020 02:33:02
User entered '17 Aug 2020 21:33'	System	18 Aug 2020 02:33:02

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:58:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 20:42'	System	17 Aug 2020 22:07:28



US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:58:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 22:07:28

**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 22:07:28
User entered 'Day 2'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:58:33

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-18T12:02:32', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '61ffe9e8-5ddc-4278-8324-1d9da43318c2'	System	18 Aug 2020 17:02:51
User entered 'None (1)'	System	18 Aug 2020 17:02:51

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:58:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-18T12:02:35', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '61ffe9e8-5ddc-4278-8324-1d9da43318c2'	System	18 Aug 2020 17:02:51
User entered 'No (N)'	System	18 Aug 2020 17:02:51

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-18T12:02:38', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '61ffe9e8-5ddc-4278-8324-1d9da43318c2'	System	18 Aug 2020 17:02:51
User entered 'No (N)'	System	18 Aug 2020 17:02:51

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:58:33

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-18T12:02:41', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '61ffe9e8-5ddc-4278-8324-1d9da43318c2'	System	18 Aug 2020 17:02:51
User entered 'None (1)'	System	18 Aug 2020 17:02:51

**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:58:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-18T12:02:43', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '61ffe9e8-5ddc-4278-8324-1d9da43318c2'	System	18 Aug 2020 17:02:51
User entered '18 Aug 2020 12:02'	System	18 Aug 2020 17:02:51

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:58:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 22:07:28



US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:58:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 22:07:28

**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 22:07:28
User entered 'Day 3'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:58:33

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-19T12:37:53', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'a94db318-d642-4bb1-afad-e0e15bc44583'	System	19 Aug 2020 17:38:05
User entered 'None (1)'	System	19 Aug 2020 17:38:05

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:58:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-19T12:37:56', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'a94db318-d642-4bb1-afad-e0e15bc44583'	System	19 Aug 2020 17:38:05
User entered 'No (N)'	System	19 Aug 2020 17:38:05

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-19T12:37:58', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'a94db318-d642-4bb1-afad-e0e15bc44583'	System	19 Aug 2020 17:38:05
User entered 'No (N)'	System	19 Aug 2020 17:38:05

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:58:33

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-19T12:38:00', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'a94db318-d642-4bb1-afad-e0e15bc44583'	System	19 Aug 2020 17:38:05
User entered 'None (1)'	System	19 Aug 2020 17:38:05

**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:58:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-19T12:38:03', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'a94db318-d642-4bb1-afad-e0e15bc44583'	System	19 Aug 2020 17:38:05
User entered '19 Aug 2020 12:38'	System	19 Aug 2020 17:38:05

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:58:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 22:07:28



**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:58:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 22:07:28

**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 22:07:28
User entered 'Day 4'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:58:33

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-20T12:38:54', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'a62bfe99-f3b0-40dd-9a1a-0dad3ec49ce2'	System	20 Aug 2020 17:39:08
User entered 'None (1)'	System	20 Aug 2020 17:39:08

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:58:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-20T12:38:57', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'a62bfe99-f3b0-40dd-9a1a-0dad3ec49ce2'	System	20 Aug 2020 17:39:08
User entered 'No (N)'	System	20 Aug 2020 17:39:08

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-20T12:38:59', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'a62bfe99-f3b0-40dd-9a1a-0dad3ec49ce2'	System	20 Aug 2020 17:39:08
User entered 'No (N)'	System	20 Aug 2020 17:39:08

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:58:33

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-20T12:39:01', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'a62bfe99-f3b0-40dd-9a1a-0dad3ec49ce2'	System	20 Aug 2020 17:39:08
User entered 'None (1)'	System	20 Aug 2020 17:39:08

**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:58:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-20T12:39:04', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'a62bfe99-f3b0-40dd-9a1a-0dad3ec49ce2'	System	20 Aug 2020 17:39:08
User entered '20 Aug 2020 12:39'	System	20 Aug 2020 17:39:08

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:58:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 22:07:28



US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:58:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 22:07:28

**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 22:07:28
User entered 'Day 5'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:58:33

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-21T12:02:02', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '97f7867f-0ca5-4a73-957a-da59be967487'	System	21 Aug 2020 17:02:19
User entered 'None (1)'	System	21 Aug 2020 17:02:19

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:58:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-21T12:02:04', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '97f7867f-0ca5-4a73-957a-da59be967487'	System	21 Aug 2020 17:02:19
User entered 'No (N)'	System	21 Aug 2020 17:02:19

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-21T12:02:06', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '97f7867f-0ca5-4a73-957a-da59be967487'	System	21 Aug 2020 17:02:19
User entered 'No (N)'	System	21 Aug 2020 17:02:19

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:58:33

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-21T12:02:08', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '97f7867f-0ca5-4a73-957a-da59be967487'	System	21 Aug 2020 17:02:19
User entered 'None (1)'	System	21 Aug 2020 17:02:19

**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:58:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-21T12:02:12', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '97f7867f-0ca5-4a73-957a-da59be967487'	System	21 Aug 2020 17:02:19
User entered '21 Aug 2020 12:02'	System	21 Aug 2020 17:02:19

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:58:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 22:07:28



US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:58:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 22:07:28

**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 22:07:28
User entered 'Day 6'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:58:33

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-22T12:01:30', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '13b6d9a6-3c25-431b-8b1f-05552802e960'	System	22 Aug 2020 17:01:39
User entered 'None (1)'	System	22 Aug 2020 17:01:39

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:58:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-22T12:01:32', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '13b6d9a6-3c25-431b-8b1f-05552802e960'	System	22 Aug 2020 17:01:39
User entered 'No (N)'	System	22 Aug 2020 17:01:39

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-22T12:01:33', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '13b6d9a6-3c25-431b-8b1f-05552802e960'	System	22 Aug 2020 17:01:39
User entered 'No (N)'	System	22 Aug 2020 17:01:39

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:58:33

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-22T12:01:35', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '13b6d9a6-3c25-431b-8b1f-05552802e960'	System	22 Aug 2020 17:01:39
User entered 'None (1)'	System	22 Aug 2020 17:01:39

**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:58:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-22T12:01:37', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '13b6d9a6-3c25-431b-8b1f-05552802e960'	System	22 Aug 2020 17:01:39
User entered '22 Aug 2020 12:01'	System	22 Aug 2020 17:01:39

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:58:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 22:07:28



US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:58:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 22:07:28

**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 22:07:28
User entered 'Day 7'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:58:33

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-23T12:11:11', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '0d0533e8-f829-4fd3-a670-9a972de74d8a'	System	23 Aug 2020 17:11:21
User entered 'None (1)'	System	23 Aug 2020 17:11:21

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:58:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-23T12:11:13', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '0d0533e8-f829-4fd3-a670-9a972de74d8a'	System	23 Aug 2020 17:11:21
User entered 'No (N)'	System	23 Aug 2020 17:11:21

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-23T12:11:15', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '0d0533e8-f829-4fd3-a670-9a972de74d8a'	System	23 Aug 2020 17:11:21
User entered 'No (N)'	System	23 Aug 2020 17:11:21

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:58:33

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-23T12:11:16', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '0d0533e8-f829-4fd3-a670-9a972de74d8a'	System	23 Aug 2020 17:11:21
User entered 'None (1)'	System	23 Aug 2020 17:11:21

**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:58:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-23T12:11:19', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '0d0533e8-f829-4fd3-a670-9a972de74d8a'	System	23 Aug 2020 17:11:21
User entered '23 Aug 2020 12:11'	System	23 Aug 2020 17:11:21

US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:58:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 22:07:28



US3342088

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:58:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 22:07:28

**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 22:07:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 22:07:28

**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:58:33**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T17:30:08', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'cb8cec67-3e47-48e4-a7f5-98cf4980d78f'	System	17 Aug 2020 22:30:35
User entered 'None (0)'	System	17 Aug 2020 22:30:35

US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:58:33

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T17:30:12', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'cb8cec67-3e47-48e4-a7f5-98cf4980d78f'	System	17 Aug 2020 22:30:35
User entered 'None (0)'	System	17 Aug 2020 22:30:35

**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:58:33**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T17:30:16', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'cb8cec67-3e47-48e4-a7f5-98cf4980d78f'	System	17 Aug 2020 22:30:35
User entered 'None (0)'	System	17 Aug 2020 22:30:35

US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:58:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T17:30:19', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'cb8cec67-3e47-48e4-a7f5-98cf4980d78f'	System	17 Aug 2020 22:30:35
User entered 'None (0)'	System	17 Aug 2020 22:30:35

US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:58:33

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T17:30:21', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'cb8cec67-3e47-48e4-a7f5-98cf4980d78f'	System	17 Aug 2020 22:30:35
User entered 'None (0)'	System	17 Aug 2020 22:30:35

**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:58:33**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T17:30:22', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'cb8cec67-3e47-48e4-a7f5-98cf4980d78f'	System	17 Aug 2020 22:30:35
User entered 'None (0)'	System	17 Aug 2020 22:30:35



US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T17:30:26', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'cb8cec67-3e47-48e4-a7f5-98cf4980d78f'	System	17 Aug 2020 22:30:35
User entered 'No (N)'	System	17 Aug 2020 22:30:35

**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:58:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T17:30:29', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'cb8cec67-3e47-48e4-a7f5-98cf4980d78f'	System	17 Aug 2020 22:30:35
User entered '17 Aug 2020 17:30'	System	17 Aug 2020 22:30:35

US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:58:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 17:17'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:58:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 19:47'	System	17 Aug 2020 22:07:28

**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 22:07:28
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:58:33

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T21:33:04', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '524f7bdc-c781-43c3-93ef-6abacaa19351'	System	18 Aug 2020 02:33:24
User entered 'None (0)'	System	18 Aug 2020 02:33:24

**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:58:33**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T21:33:06', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '524f7bdc-c781-43c3-93ef-6abacaa19351'	System	18 Aug 2020 02:33:24
User entered 'None (0)'	System	18 Aug 2020 02:33:24

US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:58:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T21:33:08', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '524f7bdc-c781-43c3-93ef-6abacaa19351'	System	18 Aug 2020 02:33:24
User entered 'None (0)'	System	18 Aug 2020 02:33:24



US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:58:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T21:33:09', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '524f7bdc-c781-43c3-93ef-6abacaa19351'	System	18 Aug 2020 02:33:24
User entered 'None (0)'	System	18 Aug 2020 02:33:24

**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:58:33**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T21:33:11', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '524f7bdc-c781-43c3-93ef-6abacaa19351'	System	18 Aug 2020 02:33:24
User entered 'None (0)'	System	18 Aug 2020 02:33:24

US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:58:33

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T21:33:12', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '524f7bdc-c781-43c3-93ef-6abacaa19351'	System	18 Aug 2020 02:33:24
User entered 'None (0)'	System	18 Aug 2020 02:33:24

US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T21:33:16', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '524f7bdc-c781-43c3-93ef-6abacaa19351'	System	18 Aug 2020 02:33:24
User entered 'No (N)'	System	18 Aug 2020 02:33:24

**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:58:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-17T21:33:18', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '524f7bdc-c781-43c3-93ef-6abacaa19351'	System	18 Aug 2020 02:33:24
User entered '17 Aug 2020 21:33'	System	18 Aug 2020 02:33:24

US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:58:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 20:42'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:58:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 22:07:28

**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 22:07:28
User entered 'Day 2'	System	17 Aug 2020 22:07:28



**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:58:33**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-18T12:02:47', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'eb72805d-57f4-443d-98d8-4ad252d3867b'	System	18 Aug 2020 17:03:03
User entered 'None (0)'	System	18 Aug 2020 17:03:03

**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:58:33**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-18T12:02:49', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'eb72805d-57f4-443d-98d8-4ad252d3867b'	System	18 Aug 2020 17:03:03
User entered 'None (0)'	System	18 Aug 2020 17:03:03

US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:58:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-18T12:02:50', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'eb72805d-57f4-443d-98d8-4ad252d3867b'	System	18 Aug 2020 17:03:03
User entered 'None (0)'	System	18 Aug 2020 17:03:03

US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:58:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-18T12:02:52', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'eb72805d-57f4-443d-98d8-4ad252d3867b'	System	18 Aug 2020 17:03:03
User entered 'None (0)'	System	18 Aug 2020 17:03:03

**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:58:33**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-18T12:02:54', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'eb72805d-57f4-443d-98d8-4ad252d3867b'	System	18 Aug 2020 17:03:03
User entered 'None (0)'	System	18 Aug 2020 17:03:03

US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:58:33

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-18T12:02:56', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'eb72805d-57f4-443d-98d8-4ad252d3867b'	System	18 Aug 2020 17:03:03
User entered 'None (0)'	System	18 Aug 2020 17:03:03

US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-18T12:02:59', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'eb72805d-57f4-443d-98d8-4ad252d3867b'	System	18 Aug 2020 17:03:03
User entered 'No (N)'	System	18 Aug 2020 17:03:03

**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:58:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-18T12:03:01', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'eb72805d-57f4-443d-98d8-4ad252d3867b'	System	18 Aug 2020 17:03:03
User entered '18 Aug 2020 12:03'	System	18 Aug 2020 17:03:03



US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:58:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:58:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 22:07:28

**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 22:07:28
User entered 'Day 3'	System	17 Aug 2020 22:07:28

**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:58:33**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-19T12:38:06', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'b702f1da-90a2-409a-a96c-1341810f25f4'	System	19 Aug 2020 17:38:26
User entered 'None (0)'	System	19 Aug 2020 17:38:26

**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:58:33**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-19T12:38:08', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'b702f1da-90a2-409a-a96c-1341810f25f4'	System	19 Aug 2020 17:38:26
User entered 'None (0)'	System	19 Aug 2020 17:38:26

US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:58:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-19T12:38:10', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'b702f1da-90a2-409a-a96c-1341810f25f4'	System	19 Aug 2020 17:38:26
User entered 'None (0)'	System	19 Aug 2020 17:38:26

US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:58:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-19T12:38:12', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'b702f1da-90a2-409a-a96c-1341810f25f4'	System	19 Aug 2020 17:38:26
User entered 'None (0)'	System	19 Aug 2020 17:38:26

US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:58:33

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-19T12:38:14', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'b702f1da-90a2-409a-a96c-1341810f25f4'	System	19 Aug 2020 17:38:26
User entered 'None (0)'	System	19 Aug 2020 17:38:26



US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:58:33

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-19T12:38:16', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'b702f1da-90a2-409a-a96c-1341810f25f4'	System	19 Aug 2020 17:38:26
User entered 'None (0)'	System	19 Aug 2020 17:38:26

US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-19T12:38:21', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'b702f1da-90a2-409a-a96c-1341810f25f4'	System	19 Aug 2020 17:38:26
User entered 'No (N)'	System	19 Aug 2020 17:38:26

**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:58:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-19T12:38:24', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'b702f1da-90a2-409a-a96c-1341810f25f4'	System	19 Aug 2020 17:38:26
User entered '19 Aug 2020 12:38'	System	19 Aug 2020 17:38:26

US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:58:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:58:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 22:07:28

**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 22:07:28
User entered 'Day 4'	System	17 Aug 2020 22:07:28

**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:58:33**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-20T12:39:07', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '316357d8-bb69-49e9-be6a-6786a16ee4e0'	System	20 Aug 2020 17:39:28
User entered 'None (0)'	System	20 Aug 2020 17:39:28

**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:58:33**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-20T12:39:09', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '316357d8-bb69-49e9-be6a-6786a16ee4e0'	System	20 Aug 2020 17:39:28
User entered 'None (0)'	System	20 Aug 2020 17:39:28



US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:58:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-20T12:39:11', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '316357d8-bb69-49e9-be6a-6786a16ee4e0'	System	20 Aug 2020 17:39:28
User entered 'None (0)'	System	20 Aug 2020 17:39:28

US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:58:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-20T12:39:13', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '316357d8-bb69-49e9-be6a-6786a16ee4e0'	System	20 Aug 2020 17:39:28
User entered 'None (0)'	System	20 Aug 2020 17:39:28

**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:58:33**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-20T12:39:15', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '316357d8-bb69-49e9-be6a-6786a16ee4e0'	System	20 Aug 2020 17:39:28
User entered 'None (0)'	System	20 Aug 2020 17:39:28

US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:58:33

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-20T12:39:17', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '316357d8-bb69-49e9-be6a-6786a16ee4e0'	System	20 Aug 2020 17:39:28
User entered 'None (0)'	System	20 Aug 2020 17:39:28

US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-20T12:39:21', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '316357d8-bb69-49e9-be6a-6786a16ee4e0'	System	20 Aug 2020 17:39:28
User entered 'No (N)'	System	20 Aug 2020 17:39:28

**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:58:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-20T12:39:24', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '316357d8-bb69-49e9-be6a-6786a16ee4e0'	System	20 Aug 2020 17:39:28
User entered '20 Aug 2020 12:39'	System	20 Aug 2020 17:39:28

US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:58:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:58:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 22:07:28



**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 22:07:28
User entered 'Day 5'	System	17 Aug 2020 22:07:28

**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:58:33**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-21T12:02:18', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'd359fa50-88e5-499a-8478-097cbce8f2a1'	System	21 Aug 2020 17:03:05
User entered 'None (0)'	System	21 Aug 2020 17:03:05

**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:58:33**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-21T12:02:29', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'd359fa50-88e5-499a-8478-097cbce8f2a1'	System	21 Aug 2020 17:03:05
User entered 'None (0)'	System	21 Aug 2020 17:03:05

US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:58:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-21T12:02:34', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'd359fa50-88e5-499a-8478-097cbce8f2a1'	System	21 Aug 2020 17:03:05
User entered 'None (0)'	System	21 Aug 2020 17:03:05

US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:58:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-21T12:02:49', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'd359fa50-88e5-499a-8478-097cbce8f2a1'	System	21 Aug 2020 17:03:05
User entered 'None (0)'	System	21 Aug 2020 17:03:05

**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:58:33**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-21T12:02:51', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'd359fa50-88e5-499a-8478-097cbce8f2a1'	System	21 Aug 2020 17:03:05
User entered 'None (0)'	System	21 Aug 2020 17:03:05

**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:58:33**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-21T12:02:54', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'd359fa50-88e5-499a-8478-097cbce8f2a1'	System	21 Aug 2020 17:03:05
User entered 'None (0)'	System	21 Aug 2020 17:03:05

US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-21T12:02:57', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'd359fa50-88e5-499a-8478-097cbce8f2a1'	System	21 Aug 2020 17:03:05
User entered 'No (N)'	System	21 Aug 2020 17:03:05



**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:58:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-21T12:03:00', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'd359fa50-88e5-499a-8478-097cbce8f2a1'	System	21 Aug 2020 17:03:05
User entered '21 Aug 2020 12:03'	System	21 Aug 2020 17:03:05

US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:58:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:58:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 22:07:28

**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 22:07:28
User entered 'Day 6'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:58:33

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-22T12:01:40', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '8cfbee8f-d883-4bff-b6a5-6103f0e08c14'	System	22 Aug 2020 17:01:56
User entered 'None (0)'	System	22 Aug 2020 17:01:56

US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:58:33

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-22T12:01:41', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '8cfbee8f-d883-4bff-b6a5-6103f0e08c14'	System	22 Aug 2020 17:01:56
User entered 'None (0)'	System	22 Aug 2020 17:01:56

US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:58:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-22T12:01:43', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '8cfbee8f-d883-4bff-b6a5-6103f0e08c14'	System	22 Aug 2020 17:01:56
User entered 'None (0)'	System	22 Aug 2020 17:01:56

US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:58:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-22T12:01:44', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '8cfbee8f-d883-4bff-b6a5-6103f0e08c14'	System	22 Aug 2020 17:01:56
User entered 'None (0)'	System	22 Aug 2020 17:01:56



**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:58:33**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-22T12:01:46', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '8cfbee8f-d883-4bff-b6a5-6103f0e08c14'	System	22 Aug 2020 17:01:56
User entered 'None (0)'	System	22 Aug 2020 17:01:56

US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:58:33

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-22T12:01:47', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '8cfbee8f-d883-4bff-b6a5-6103f0e08c14'	System	22 Aug 2020 17:01:56
User entered 'None (0)'	System	22 Aug 2020 17:01:56

US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-22T12:01:49', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '8cfbee8f-d883-4bff-b6a5-6103f0e08c14'	System	22 Aug 2020 17:01:56
User entered 'No (N)'	System	22 Aug 2020 17:01:56

**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:58:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-22T12:01:52', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '8cfbee8f-d883-4bff-b6a5-6103f0e08c14'	System	22 Aug 2020 17:01:56
User entered '22 Aug 2020 12:01'	System	22 Aug 2020 17:01:56

US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:58:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 22:07:28

US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:58:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 22:07:28

**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 22:07:28
User entered 'Day 7'	System	17 Aug 2020 22:07:28

**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:58:33**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-23T12:11:21', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'bfb5ec13-5429-49e8-bcbf-82d1db68c9e2'	System	23 Aug 2020 17:11:37
User entered 'None (0)'	System	23 Aug 2020 17:11:37



US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:58:33

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-23T12:11:23', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'bfb5ec13-5429-49e8-bcbf-82d1db68c9e2'	System	23 Aug 2020 17:11:37
User entered 'None (0)'	System	23 Aug 2020 17:11:37

US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:58:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-23T12:11:24', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'bfb5ec13-5429-49e8-bcbf-82d1db68c9e2'	System	23 Aug 2020 17:11:37
User entered 'None (0)'	System	23 Aug 2020 17:11:37

US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:58:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-23T12:11:26', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'bfb5ec13-5429-49e8-bcbf-82d1db68c9e2'	System	23 Aug 2020 17:11:37
User entered 'None (0)'	System	23 Aug 2020 17:11:37

**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:58:33**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-23T12:11:27', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'bfb5ec13-5429-49e8-bcbf-82d1db68c9e2'	System	23 Aug 2020 17:11:37
User entered 'None (0)'	System	23 Aug 2020 17:11:37

**US3342088**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:58:33**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-23T12:11:29', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'bfb5ec13-5429-49e8-bcbf-82d1db68c9e2'	System	23 Aug 2020 17:11:37
User entered 'None (0)'	System	23 Aug 2020 17:11:37

US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-23T12:11:32', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'bfb5ec13-5429-49e8-bcbf-82d1db68c9e2'	System	23 Aug 2020 17:11:37
User entered 'No (N)'	System	23 Aug 2020 17:11:37

US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:58:33

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-08-23T12:11:34', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'bfb5ec13-5429-49e8-bcbf-82d1db68c9e2'	System	23 Aug 2020 17:11:37
User entered '23 Aug 2020 12:11'	System	23 Aug 2020 17:11:37

US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:58:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 22:07:28



US3342088

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:58:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 22:07:28

US3342088

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:58:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	24 Aug 2020 20:39:29

US3342088

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered '24 Aug 2020'	Ethan Shotton (b) (4) (b) (4)	24 Aug 2020 20:39:29

US3342088

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:58:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4) (b) (4)	24 Aug 2020 20:39:29

**US3342088**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:58:33**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	Ethan Shotton (b) (4) (b) (4)	24 Aug 2020 20:39:29

US3342088

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	24 Aug 2020 20:39:33

**US3342088**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:58:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Aug 2020 20:39:33

US3342088

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:58:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	31 Aug 2020 16:41:29



US3342088

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered '31 Aug 2020'	Ethan Shotton (b) (4) (b) (4)	31 Aug 2020 16:41:29

US3342088

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:58:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4) (b) (4)	31 Aug 2020 16:41:29

US3342088

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:58:33

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	Ethan Shotton (b) (4) (b) (4)	31 Aug 2020 16:41:29

US3342088

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	31 Aug 2020 16:41:32

**US3342088**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:58:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	31 Aug 2020 16:41:32

US3342088

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:58:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	08 Sep 2020 23:26:34

US3342088

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered '8 Sep 2020'	Ethan Shotton (b) (4) (b) (4)	08 Sep 2020 23:26:34

US3342088

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:58:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4) (b) (4)	08 Sep 2020 23:26:34



US3342088

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:58:33

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	Ethan Shotton (b) (4) (b) (4)	08 Sep 2020 23:26:34

US3342088

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	08 Sep 2020 23:26:38

**US3342088**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:58:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Sep 2020 23:26:38

US3342088

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:58:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	17 Sep 2020 22:12:55

US3342088

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:58:33

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 14OCT2020 is reported under Visit 3 Day 57 visit in PPD central lab, however Immunogenicity Assessment form is not completed in EDC. Please complete, else clarify. Thank you. '(Site from DM).	(b) (4), (b) (6)	25 Nov 2020 03:25:00
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 14OCT2020 is reported under Visit 3 Day 57 visit in PPD central lab, however Immunogenicity Assessment form is not completed in EDC. Please complete, else clarify. Thank you. ' answered with 'Immunogenicity Assessment form updated on EDC.' (Site from DM).	Ethan Shotton (b) (4) (b) (4)	05 Nov 2020 22:34:46
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 14OCT2020 is reported under Visit 3 Day 57 visit in PPD central lab, however Immunogenicity Assessment form is not completed in EDC. Please complete, else clarify. Thank you. '(Site from DM).	(b) (4), (b) (6)	02 Nov 2020 11:08:25
User entered '17 Sep 2020'	Morgan Schulle (b) (4) (b) (4)	17 Sep 2020 22:12:55

US3342088

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Morgan Schulle (b) (4) (b) (4)	17 Sep 2020 22:12:55

**US3342088**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:58:33**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	17 Sep 2020 22:12:55

US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:33

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:17:55



US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:33

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:17:55

US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '17 Sep 2020'	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:17:55

US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered '13:41'	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:17:55

**US3342088**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:58:33**

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

Audit	User	Time (GMT)
User entered '17 Sep 2020 13:41'	System	02 Oct 2020 18:17:55

US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:33

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.7' F	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:17:55

US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:33

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:17:55

US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:33

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:17:55

US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:33

Pulse (xxx)

Audit	User	Time (GMT)
User entered '64'	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:17:55



US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:33

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	02 Oct 2020 18:17:55

US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered '14'	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:17:55

US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	02 Oct 2020 18:17:55

US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '110'	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:17:55

US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Oct 2020 18:17:55

US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '76'	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:17:55

US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:58:33

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Oct 2020 18:17:55

US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:58:33

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:17:55



US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:58:33

Were vital signs assessed?

Audit	User	Time (GMT)
User closed query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	System	02 Oct 2020 18:18:09
User opened query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	System	02 Oct 2020 18:17:55
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:17:55

US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:58:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:17:55

US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:17:55

**US3342088**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:58:33**

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

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 18:17:55

US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:58:33

Temperature (xxx.x)

Audit	User		Time (GMT)
User entered empty; reason for change Data Entry Error	Eileen Euperio	(b) (4)	02 Oct 2020 18:18:09
	(b) (4)		
User entered missing code ND - Not Done.	Eileen Euperio	(b) (4)	02 Oct 2020 18:17:55
	(b) (4)		

US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:58:33

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:17:55

US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:58:33

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:17:55

US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:58:33

[Pulse \(xxx\)](#)

Audit	User		Time (GMT)
User entered empty; reason for change Data Entry Error	Eileen Euperio	(b) (4)	02 Oct 2020 18:18:09
	(b) (4)		
User entered missing code ND - Not Done.	Eileen Euperio	(b) (4)	02 Oct 2020 18:17:55
	(b) (4)		



**US3342088**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:58:33**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 18:18:09
User entered 'bpm'	System	02 Oct 2020 18:17:55

US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:58:33

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

Audit	User		Time (GMT)
User entered empty; reason for change Data Entry Error	Eileen Euperio (b) (4)	(b) (4)	02 Oct 2020 18:18:09
User entered missing code ND - Not Done.	Eileen Euperio (b) (4)	(b) (4)	02 Oct 2020 18:17:55

US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:58:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 18:18:09
User entered 'breaths/min'	System	02 Oct 2020 18:17:55

US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Eileen Euperio (b) (4)	02 Oct 2020 18:18:09
User entered missing code ND - Not Done.	Eileen Euperio (b) (4)	02 Oct 2020 18:17:55

US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:58:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 18:18:09
User entered 'mmHg'	System	02 Oct 2020 18:17:55

US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:58:33

Diastolic Blood Pressure (xxx)

Audit	User		Time (GMT)
User entered empty; reason for change Data Entry Error	Eileen Euperio	(b) (4)	02 Oct 2020 18:18:09
	(b) (4)		
User entered missing code ND - Not Done.	Eileen Euperio	(b) (4)	02 Oct 2020 18:17:55
	(b) (4)		

US3342088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:58:33

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 18:18:09
User entered 'mmHg'	System	02 Oct 2020 18:17:55

US3342088

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:58:33

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:18:24



US3342088

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:58:33

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '17 Sep 2020'	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:18:24

US3342088

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:58:33

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:18:40

US3342088

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:58:33

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '17 Sep 2020'	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:18:40

US3342088

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:58:33

[Test performed](#)

Audit	User	Time (GMT)
User entered 'Urine (URINE)'	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:18:40

US3342088

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:58:33

[Result](#)

Audit	User	Time (GMT)
User entered 'Negative (NEGATIVE)'	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:18:40

US3342088

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:58:33

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:18:40

US3342088

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:58:33

[Collection date](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:18:40

US3342088

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:58:33

[Collection time](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:18:40



US3342088

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 18:18:40

US3342088

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:58:33

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:19:27

US3342088

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:58:33

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered 'Physician Decision (PHYSICIAN DECISION)'	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:19:27

US3342088

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered 'SAE new dx of colon cancer'	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:19:27

US3342088

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:58:33

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 18:19:27

US3342088

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:58:33

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:19:27

US3342088

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:19:27

US3342088

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 18:19:27



US3342088

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:58:33

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:19:27

US3342088

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:58:33

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 18:19:27

US3342088

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:58:33

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 18:19:27

US3342088

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:58:33

Was the sample collected?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	17 Sep 2020 22:12:27

US3342088

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:58:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '17 Sep 2020'	Morgan Schulle (b) (4) (b) (4)	17 Sep 2020 22:12:27

US3342088

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:58:33

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '14:12'	Morgan Schulle (b) (4) (b) (4)	17 Sep 2020 22:12:27

**US3342088**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:58:33**

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

Audit	User	Time (GMT)
User entered '17 Sep 2020 14:12'	System	17 Sep 2020 22:12:27

US3342088

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:58:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '17 Sep 2020'	Morgan Schulle (b) (4) (b) (4)	17 Sep 2020 22:12:42



US3342088

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:58:33

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Morgan Schulle (b) (4) (b) (4)	17 Sep 2020 22:12:42

US3342088

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:58:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	17 Sep 2020 22:12:42

US3342088

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:58:33

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '14:13'	Morgan Schulle (b) (4) (b) (4)	17 Sep 2020 22:12:42

US3342088

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered '17 Sep 2020 14:13'	System	17 Sep 2020 22:12:42

US3342088

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:58:33

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Morgan Schulle (b) (4)	17 Sep 2020 22:12:42

US3342088

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:58:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	17 Sep 2020 22:12:42

US3342088

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:58:33

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Morgan Schulle (b) (4) (b) (4)	17 Sep 2020 22:12:42

**US3342088**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 10:58:33**

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

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 22:12:42



US3342088

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	30 Sep 2020 22:14:36

US3342088

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:58:33

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Sep 2020 22:14:36

US3342088

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:58:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	01 Oct 2020 21:24:33

US3342088

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered '24 Sep 2020'	Eileen Euperio (b) (4) (b) (4)	01 Oct 2020 21:24:33

US3342088

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:58:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Not Made (CONTACT NOT MADE)'	Eileen Euperio (b) (4) (b) (4)	01 Oct 2020 21:24:33

US3342088

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:58:33

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered 'VM left on 24sep2020, 25sep2020, and Eileen Euperio 28sep2020'	(b) (4) (b) (4)	01 Oct 2020 21:24:33

US3342088

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	01 Oct 2020 21:24:38

**US3342088**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:58:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Oct 2020 21:24:38



US3342088

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:58:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:19:41

US3342088

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered '2 Oct 2020'	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:19:41

US3342088

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:58:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:19:41

US3342088

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:58:33

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:19:41

US3342088

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:19:47

**US3342088**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:58:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Oct 2020 18:19:47

US3342088

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:58:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	05 Nov 2020 22:08:05

US3342088

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered '9 Oct 2020'	Ethan Shotton (b) (4) (b) (4)	05 Nov 2020 22:08:05



US3342088

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:58:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4) (b) (4)	05 Nov 2020 22:08:05

**US3342088**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:58:33**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	Ethan Shotton (b) (4) (b) (4)	05 Nov 2020 22:08:05

US3342088

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	05 Nov 2020 22:08:30

**US3342088**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:58:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Nov 2020 22:08:30

US3342088

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:58:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	05 Nov 2020 22:09:53

US3342088

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered '14 Oct 2020'	Ethan Shotton (b) (4) (b) (4)	05 Nov 2020 22:09:53

US3342088

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Ethan Shotton (b) (4) (b) (4)	05 Nov 2020 22:09:53

**US3342088**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:58:33**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	05 Nov 2020 22:09:53



US3342088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	05 Nov 2020 22:11:02

US3342088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '14 Oct 2020'	Ethan Shotton (b) (4) (b) (4)	05 Nov 2020 22:11:02

US3342088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered '13:13'	Ethan Shotton (b) (4) (b) (4)	05 Nov 2020 22:11:02

US3342088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered '14 Oct 2020 13:13'	System	05 Nov 2020 22:11:02

US3342088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:33

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.7' F	Ethan Shotton (b) (4) (b) (4)	05 Nov 2020 22:11:02

US3342088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:33

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Ethan Shotton (b) (4) (b) (4)	05 Nov 2020 22:11:02

US3342088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:33

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Ethan Shotton (b) (4) (b) (4)	05 Nov 2020 22:11:02

US3342088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '71'	Ethan Shotton (b) (4) (b) (4)	05 Nov 2020 22:11:02



**US3342088**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:58:33**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	05 Nov 2020 22:11:02

US3342088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered '12'	Ethan Shotton (b) (4) (b) (4)	05 Nov 2020 22:11:02

US3342088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	05 Nov 2020 22:11:02

US3342088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '106'	Ethan Shotton (b) (4) (b) (4)	05 Nov 2020 22:11:02

US3342088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Nov 2020 22:11:02

US3342088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '70'	Ethan Shotton (b) (4) (b) (4)	05 Nov 2020 22:11:02

US3342088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:58:33

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Nov 2020 22:11:02

US3342088

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:58:33

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	Ethan Shotton (b) (4) (b) (4)	05 Nov 2020 22:11:08



US3342088

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:58:33

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Ethan Shotton (b) (4) (b) (4)	05 Nov 2020 22:11:08

US3342088

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:58:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	05 Nov 2020 22:15:23

US3342088

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:58:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '14 Oct 2020'	Ethan Shotton (b) (4) (b) (4)	05 Nov 2020 22:15:23

US3342088

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:58:33

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '14:02'	Ethan Shotton (b) (4) (b) (4)	05 Nov 2020 22:15:23

US3342088

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered '14 Oct 2020 14:02'	System	05 Nov 2020 22:15:23

US3342088

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	05 Nov 2020 22:15:27

**US3342088**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:58:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Nov 2020 22:15:27

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 22:07:28
User entered 'Day 64'	System	17 Aug 2020 22:07:28



**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[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 (2486ccab664d35e9)', Time: '2020-10-18T08:23:00', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '799a230f-eb78-4d20-8789-89b05503097f'	System	18 Oct 2020 13:23:12
User entered 'No (N)'	System	18 Oct 2020 13:23:12

US3342088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

Have you been exposed to someone with 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 (2486ccab664d35e9)', Time: '2020-10-18T08:23:03', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '799a230f-eb78-4d20-8789-89b05503097f'	System	18 Oct 2020 13:23:12
User entered 'No (N)'	System	18 Oct 2020 13:23:12

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-10-18T08:23:07', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '799a230f-eb78-4d20-8789-89b05503097f' User entered '18 Oct 2020 08:23:07'	System	18 Oct 2020 13:23:12
	System	18 Oct 2020 13:23:12

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 22:07:28
User entered '17 Oct 2020 00:01'	System	17 Aug 2020 22:07:28

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 22:07:28
User entered '21 Oct 2020 23:59'	System	17 Aug 2020 22:07:28

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 22:07:28
User entered 'Day 71'	System	17 Aug 2020 22:07:28

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[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 (2486ccab664d35e9)', Time: '2020-10-28T21:58:17', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '705df78f-9259-4763-8e20-d39d6f047000'	System	29 Oct 2020 02:58:35
User entered 'No (N)'	System	29 Oct 2020 02:58:35

US3342088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

Have you been exposed to someone with 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 (2486ccab664d35e9)', Time: '2020-10-28T21:58:22', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '705df78f-9259-4763-8e20-d39d6f047000'	System	29 Oct 2020 02:58:35
User entered 'No (N)'	System	29 Oct 2020 02:58:35



**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-10-28T21:58:27', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '705df78f-9259-4763-8e20-d39d6f047000'	System	29 Oct 2020 02:58:35
User entered '28 Oct 2020 21:58:27'	System	29 Oct 2020 02:58:35

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 22:07:28
User entered '24 Oct 2020 00:01'	System	17 Aug 2020 22:07:28

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 22:07:28
User entered '28 Oct 2020 23:59'	System	17 Aug 2020 22:07:28

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 22:07:28
User entered 'Day 78'	System	17 Aug 2020 22:07:28

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[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 (2486ccab664d35e9)', Time: '2020-10-31T08:45:21', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'e5ab363e-ef5d-4591-9ca3-fef3cbdeb2a8'	System	31 Oct 2020 13:45:38
User entered 'No (N)'	System	31 Oct 2020 13:45:38

US3342088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

Have you been exposed to someone with 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 (2486ccab664d35e9)', Time: '2020-10-31T08:45:28', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'e5ab363e-ef5d-4591-9ca3-fef3cbdeb2a8'	System	31 Oct 2020 13:45:38
User entered 'No (N)'	System	31 Oct 2020 13:45:38

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-10-31T08:45:31', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: 'e5ab363e-ef5d-4591-9ca3-fef3cbdeb2a8' User entered '31 Oct 2020 08:45:31'	System	31 Oct 2020 13:45:38
	System	31 Oct 2020 13:45:38

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 22:07:28
User entered '31 Oct 2020 00:01'	System	17 Aug 2020 22:07:28



**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 22:07:28
User entered '04 Nov 2020 23:59'	System	17 Aug 2020 22:07:28

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 22:07:28
User entered 'Day 92'	System	17 Aug 2020 22:07:28

US3342088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

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 (2486ccab664d35e9)', Time: '2020-11-16T12:06:03', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '6b3be40c-c559-49c4-9c83-c8843baf9acd'	System	16 Nov 2020 18:06:36
User entered 'No (N)'	System	16 Nov 2020 18:06:36

US3342088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:58:33

Have you been exposed to someone with 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 (2486ccab664d35e9)', Time: '2020-11-16T12:06:25', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '6b3be40c-c559-49c4-9c83-c8843baf9acd'	System	16 Nov 2020 18:06:36
User entered 'No (N)'	System	16 Nov 2020 18:06:36

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2486ccab664d35e9)', Time: '2020-11-16T12:06:33', User OID: 'PatientReportedOutcome (US3342088)', ODM File OID: '6b3be40c-c559-49c4-9c83-c8843baf9acd'	System	16 Nov 2020 18:06:36
User entered '16 Nov 2020 12:06:33'	System	16 Nov 2020 18:06:36

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 22:07:28
User entered '14 Nov 2020 00:01'	System	17 Aug 2020 22:07:28

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 22:07:28
User entered '18 Nov 2020 23:59'	System	17 Aug 2020 22:07:28

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 09:46:18



**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '14 Oct 2020 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '18 Oct 2020 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '21 Oct 2020 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '25 Oct 2020 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '28 Oct 2020 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '01 Nov 2020 23:59'	System	19 Nov 2020 09:46:18



**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '04 Nov 2020 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '08 Nov 2020 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '11 Nov 2020 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '15 Nov 2020 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 09:46:18



**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 09:46:18



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 09:46:18



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 09:46:18



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 09:46:18



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 09:46:18



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 09:46:18

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 09:46:18



**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 09:46:18



**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 09:46:18



**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 09:46:18



**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 09:46:18



**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 09:46:18



**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 09:46:18



**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 09:46:18



**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 09:46:18



**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 09:46:18



**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 09:46:18



**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 09:46:18



**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 09:46:18



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 09:46:18

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 09:46:18



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 09:46:18



**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 09:46:18



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 09:46:18



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 09:46:18



**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 09:46:18



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 09:46:18



**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 09:46:18



**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 09:46:18

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 09:46:18

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 09:46:18

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 09:46:18



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 09:46:18

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 09:46:18

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 09:46:18

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 09:46:18

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 09:46:18

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 09:46:18



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 09:46:18

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 09:46:18

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 09:46:18

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 09:46:18

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 09:46:18

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 09:46:18

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 09:46:18

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 09:46:18



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 09:46:18

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 09:46:18

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 09:46:18

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 09:46:18

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 09:46:18

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 09:46:18

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 09:46:18

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 09:46:18



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 09:46:18

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 09:46:18

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 09:46:18

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 09:46:18

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 09:46:18

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 09:46:18



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 09:46:18

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 09:46:18

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 09:46:18

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 09:46:18

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

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**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 09:46:18

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 09:46:18

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 09:46:18



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 09:46:18

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 09:46:18

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 09:46:18

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 09:46:18

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 09:46:18

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

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**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 09:46:18



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

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 09:46:18

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 09:46:18

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

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**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 09:46:18

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

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**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 09:46:18

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 09:46:18

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

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 09:46:18

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

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**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 09:46:18

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 09:46:18



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

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**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 09:46:18

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 09:46:18

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 09:46:18



**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 09:46:18



**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 09:46:18



**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '19 Oct 2022 00:01'	System	19 Nov 2020 09:46:18

**US3342088**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:58:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:46:18
Amendment Manager: User entered '23 Oct 2022 23:59'	System	19 Nov 2020 09:46:18

US3342088

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:58:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Nov 2020 17:35:21

US3342088

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered '9 Nov 2020'	(b) (4), (b) (6)	09 Nov 2020 17:35:21

US3342088

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:58:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	09 Nov 2020 17:35:21



US3342088

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:58:33

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 17:35:21

US3342088

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Nov 2020 17:35:27

**US3342088**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:58:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Nov 2020 17:35:27

US3342088

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:58:33

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:08:12
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	17 Sep 2020 22:02:19

US3342088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:33

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:19:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:00
User entered 'USA-US203-2020-mRNA-1273-P301000001'	System	18 Sep 2020 16:03:52
User entered 'New'	(b) (4), (b) (6)	18 Sep 2020 16:03:52

US3342088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:33

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:19:43
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Gastrointestinal neoplasms malignant and unspecified, HLT: Colorectal neoplasms malignant, PT: Colon cancer stage III, LLT: Colon cancer stage III - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 20:05:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	14 Oct 2020 20:05:32
Data point term sent to Coder	System	14 Oct 2020 20:04:23
Coding entries removed.	Darrell O'Brien (b) (4)	14 Oct 2020 20:04:22
User entered 'Stage III COLON CANCER' reason for change: Data Entry Error	(b) (4)	14 Oct 2020 20:04:22
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Gastrointestinal neoplasms malignant and unspecified, HLT: Colorectal neoplasms malignant, PT: Colon cancer, LLT: Colon cancer - version MedDRA\\23.0.	Darrell O'Brien (b) (4)	14 Oct 2020 20:04:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 22:06:43
Data point term sent to Coder	(b) (4)	17 Sep 2020 22:06:17
User entered 'Colon Cancer'	System	17 Sep 2020 22:06:02
	Eileen Euperio (b) (4)	
	(b) (4)	

US3342088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:33

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:19:43
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	17 Sep 2020 22:06:02

US3342088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:33

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:19:43
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	17 Sep 2020 22:06:02



US3342088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:33

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:19:43
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	17 Sep 2020 22:06:02

US3342088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:33

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:19:43
User entered '15 Sep 2020'	Eileen Euperio (b) (4) (b) (4)	17 Sep 2020 22:06:02

US3342088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:33

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:19:43
User entered empty.	Eileen Euperio (b) (4)	17 Sep 2020 22:06:02
	(b) (4)	

**US3342088**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:58:33**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 22:06:02

US3342088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:33

[Ongoing?](#)

Audit	User	Time (GMT)
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)	06 Nov 2020 16:41:00
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 'Will do.' (Site from Safety).	Ethan Shotton (b) (4)	05 Nov 2020 22:20:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:19:43
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)	15 Oct 2020 13:56:14
User entered 'Yes (Y)'	Eileen Euperio (b) (4)	17 Sep 2020 22:06:02

US3342088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:33

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:19:43
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)	12 Oct 2020 15:09:54
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 'ongoing' (Site from Safety).	Eileen Euperio (b) (4)	09 Oct 2020 22:03:11
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)	25 Sep 2020 15:16:30
User entered empty.	Eileen Euperio (b) (4)	17 Sep 2020 22:06:02

US3342088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:33

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:19:43
User entered empty.	Eileen Euperio (b) (4)	17 Sep 2020 22:06:02
	(b) (4)	

**US3342088**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:58:33**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 22:06:02



US3342088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:33

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:19:43
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Eileen Euperio (b) (4) (b) (4)	17 Sep 2020 22:06:02

US3342088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:33

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:19:43
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	17 Sep 2020 22:06:02

US3342088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:33

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:19:43
User entered '0'	Eileen Euperio (b) (4)	17 Sep 2020 22:06:02
	(b) (4)	

US3342088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:33

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:19:43
User entered '0'	Eileen Euperio (b) (4) (b) (4)	17 Sep 2020 22:06:02

US3342088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:19:43
User entered '0'	Eileen Euperio (b) (4) (b) (4)	17 Sep 2020 22:06:02

US3342088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:33

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:19:43
User entered empty.	Eileen Euperio (b) (4)	17 Sep 2020 22:06:02
	(b) (4)	

US3342088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:33

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:19:43
User entered empty.	Eileen Euperio (b) (4)	17 Sep 2020 22:06:02
	(b) (4)	

US3342088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:33

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:19:43
User entered empty.	Eileen Euperio (b) (4)	17 Sep 2020 22:06:02
	(b) (4)	



US3342088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:33

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:19:43
User entered empty.	Eileen Euperio (b) (4)	17 Sep 2020 22:06:02
	(b) (4)	

US3342088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:19:43
User entered '0'	Eileen Euperio (b) (4) (b) (4)	17 Sep 2020 22:06:02

US3342088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:19:43
User entered '0'	Eileen Euperio (b) (4)	17 Sep 2020 22:06:02
	(b) (4)	

US3342088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:33

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:19:43
User entered '1'	Eileen Euperio (b) (4)	17 Sep 2020 22:06:02
	(b) (4)	

US3342088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:33

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:19:43
Query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	25 Sep 2020 13:23:44
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	17 Sep 2020 22:06:02
User entered 'Not Related (NOT RELATED)'	Eileen Euperio (b) (4) (b) (4)	17 Sep 2020 22:06:02

US3342088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:33

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:19:43
User entered 'Not Related (NOT RELATED)'	Eileen Euperio (b) (4) (b) (4)	17 Sep 2020 22:06:02

US3342088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:33

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. However, there is no corresponding End of Study/Discontinuation record that match this information. Please update applicable details as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 14:30:26
Query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. However, there is no corresponding End of Study/Discontinuation record that match this information. Please update applicable details as appropriate. Otherwise, clarify. ' answered with 'Per CRF guidelines, subject is does not meet necessary criteria to withdraw from the study. Subject has discontinued dosing, but is still participating in the study and attending all visits.' (Site from DM).	Ethan Shotton (b) (4) (b) (4)	05 Nov 2020 22:32:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:19:43
User opened query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. However, there is no corresponding End of Study/Discontinuation record that match this information. Please update applicable details as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 08:42:47
User closed query 'Per CDM: Since subject withdrawn from the study, then please kindly consider completing "End of Study" forms. Thank you!' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 06:10:04
Query 'Per CDM: Since subject withdrawn from the study, then please kindly consider completing "End of Study" forms. Thank you!' answered with 'updated dosing discontinuation form' (Site from DM).	Eileen Euperio (b) (4) (b) (4)	25 Sep 2020 13:41:16
User opened query 'Per CDM: Since subject withdrawn from the study, then please kindly consider completing "End of Study" forms. Thank you!' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 11:56:19
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Eileen Euperio (b) (4) (b) (4)	17 Sep 2020 22:06:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:33

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:30:07
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Procedure recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 14:30:38
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Procedure recorded that matches this AE during this timeframe. Please review and update this field.' answered with 'Updated' (Site from DM).	Darrell O'Brien (b) (4)	05 Nov 2020 16:20:04
DataPoint Un-verified.	(b) (4)	05 Nov 2020 16:19:41
User entered '0' reason for change: Data Entry Error	Darrell O'Brien (b) (4)	05 Nov 2020 16:19:41
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Procedure recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 01:30:08
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:19:43
User entered '1'	Eileen Euperio (b) (4)	17 Sep 2020 22:06:02



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:33

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:19:43
User entered '0'	Eileen Euperio (b) (4) (b) (4)	17 Sep 2020 22:06:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:33

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:30:07
User closed query 'Per CDM: Concomitant Procedure is not checked, however a procedure has been added for "Colon Cancer". Please review and clarify or update accordingly.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 14:30:40
Query 'Per CDM: Concomitant Procedure is not checked, however a procedure has been added for "Colon Cancer". Please review and clarify or update accordingly.' answered with 'Updated' (Site from DM).	Darrell O'Brien (b) (4)	05 Nov 2020 16:20:09
DataPoint Un-verified.	(b) (4)	05 Nov 2020 16:19:41
User entered '1' reason for change: Data Entry Error	Darrell O'Brien (b) (4)	05 Nov 2020 16:19:41
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:19:43
User opened query 'Per CDM: Concomitant Procedure is not checked, however a procedure has been added for "Colon Cancer". Please review and clarify or update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 16:14:20
User entered '0'	Eileen Euperio (b) (4)	17 Sep 2020 22:06:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:33

[Outcome](#)

Audit	User	Time (GMT)
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)	10 Nov 2020 15:08:04
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 'Colon Cancer is not expected to completely resolve during subject's participation in this study' (Site from Safety).	Eileen Euperio (b) (4)	09 Nov 2020 17:12:45
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:19:43
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).	(b) (4), (b) (6)	15 Oct 2020 13:56:33
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)	12 Oct 2020 15:10:01
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).	Eileen Euperio (b) (4)	09 Oct 2020 22:03:40
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Eileen Euperio (b) (4)	09 Oct 2020 22:03:33
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).	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Sep 2020 22:09:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Sep 2020 22:09:38

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:33

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Eileen Euperio (b) (4)	17 Sep 2020 22:09:38
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Sep 2020 22:06:02
User entered empty.	Eileen Euperio (b) (4)	17 Sep 2020 22:06:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:33

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:19:43
User entered empty.	Eileen Euperio (b) (4)	17 Sep 2020 22:06:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:33

[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)	20 Nov 2020 15:21:45
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 'REDATCTED RECORDS SENT VIA FAX 19NOV2020' (Site from Safety).	Eileen Euperio (b) (4) (b) (4)	19 Nov 2020 21:17:45
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)	13 Nov 2020 19:09:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:30:07
User closed query 'PV query: Please clarify if the colon cancer was identified during routine screening, or if there were symptoms that prompted the evaluation for and diagnosis of colon cancer.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 16:41:23
User closed query 'PV Query: Please confirm the date of the tumor resection. Was the date 30 Sep 2020?' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 16:41:21
User closed query 'PV Query: Please provide pathology report, if available.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 16:41:19
User closed query 'PV Query: Did the subject have any risk factors for colon cancer (i.e. cigarette smoking, family history, polyps, alcohol, etc)?' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 16:41:18
User closed query 'PV Query: Please provide initial signs/symptoms experienced by subject with date of onset.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 16:41:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:33

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide treatment given for the event including surgical treatments (including date and name of curative surgery). 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)	06 Nov 2020 16:41:14
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)	06 Nov 2020 16:41:12
User closed query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 16:41:10
Query 'PV Query: Please provide initial signs/symptoms experienced by subject with date of onset.' answered with 'No initial s/s.' (Site from Safety).	Darrell O'Brien (b) (4)	05 Nov 2020 18:31:06
Query 'PV query: Please clarify if the colon cancer was identified during routine screening, or if there were symptoms that prompted the evaluation for and diagnosis of colon cancer.' answered with 'Routine screening.' (Site from Safety).	Darrell O'Brien (b) (4)	05 Nov 2020 18:30:54
Query 'PV Query: Please provide pathology report, if available.' answered with 'Pathology report: invasive colonic adenocarcinoma 30SEP2020. ' (Site from Safety).	Darrell O'Brien (b) (4)	05 Nov 2020 18:28:03
Query 'PV Query: Did the subject have any risk factors for colon cancer (i.e. cigarette smoking, family history, polyps, alcohol, etc)?' answered with 'Family history of breast cancer.' (Site from Safety).	Darrell O'Brien (b) (4)	05 Nov 2020 18:25:50
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Sigmoid cancer from pathology report of biopsy of polyp removed from sigmoidal colon on 30SEP2020. ' (Site from Safety).	Darrell O'Brien (b) (4)	05 Nov 2020 18:23:59

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:33

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please confirm the date of the tumor resection. Was the date 30 Sep 2020?' answered with 'Confirmed' (Site from Safety).	Darrell O'Brien (b) (4)	05 Nov 2020 16:29:27
User entered 'PATIENT DIAGNOSED WITH COLON CANCER ON 15SEP2020. NO STAGE WAS DETERMINED AND SURGERY HAS YET TO BE SCHEDULED. PATIENT SAYS CHEMOTHERAPY IS NOT EXPECTED AND SHOULD ONLY REQUIRE SURGERY. PATIENT UNDERWENT COLONIC TUMOR RESECTION WITH ILEOSTOMY ON 30SEP2020 (NOTED IN SOURCE 16OCT2020 PROGRESS NOTE). CON MEDICATION GIVEN FOR POST OPERATIVE PAIN MANAGEMENT (700MG ACETAMINOPHEN QID/PRN PO [ START 30SEP2020, END 03OCT2020 ] ). UPDATED CON MED LIST. DAO 05NOV2020.' reason for change: New Information	Darrell O'Brien (b) (4)	05 Nov 2020 16:29:13
Query 'PV Query: Please provide treatment given for the event including surgical treatments (including date and name of curative surgery). Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' answered with 'Updated' (Site from Safety).	Darrell O'Brien (b) (4)	05 Nov 2020 16:27:59
Query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' answered with 'Updated' (Site from Safety).	Darrell O'Brien (b) (4)	05 Nov 2020 16:27:48



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:33

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PATIENT DIAGNOSED WITH COLON CANCER ON 15SEP2020. NO STAGE WAS DETERMINED AND SURGERY HAS YET TO BE SCHEDULED. PATIENT SAYS CHEMOTHERAPY IS NOT EXPECTED AND SHOULD ONLY REQUIRE SURGERY. PATIENT UNDERWENT COLONIC TUMOR RESECTION WITH ILEOSTOMY ON 30SEP2020 (NOTED IN SOURCE 16OCT2020 Progress note). Con medication given for post operative pain management (700mg Acetaminophen PRN PO [ Start 30SEP2020, End 03OCT2020 ] ). Updated con med list. DAO 05NOV2020.' reason for change: New Information DataPoint Un-verified.	Darrell O'Brien (b) (4) (b) (4)	05 Nov 2020 16:27:40
	Darrell O'Brien (b) (4) (b) (4)	05 Nov 2020 16:24:48
User entered 'PATIENT DIAGNOSED WITH COLON CANCER ON 15SEP2020. NO STAGE WAS DETERMINED AND SURGERY HAS YET TO BE SCHEDULED. PATIENT SAYS CHEMOTHERAPY IS NOT EXPECTED AND SHOULD ONLY REQUIRE SURGERY. Patient underwent Colonic Tumor Resection with Ileostomy on 30SEP2020 (noted in source 16OCT2020' reason for change: New Information DataPoint Verified.	Darrell O'Brien (b) (4) (b) (4)	05 Nov 2020 16:24:48
	(b) (4), (b) (6)	27 Oct 2020 17:19:43
User opened query 'PV query: Please clarify if the colon cancer was identified during routine screening, or if there were symptoms that prompted the evaluation for and diagnosis of colon cancer.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 13:59:36
User opened query 'PV Query: Please confirm the date of the tumor resection. Was the date 30 Sep 2020?' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 13:59:15
User opened query 'PV Query: Please provide pathology report, if available.' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 15:17:51
User opened query 'PV Query: Did the subject have any risk factors for colon cancer (i.e. cigarette smoking, family history, polyps, alcohol, etc)?' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 15:17:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:58:33

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide initial signs/symptoms experienced by subject with date of onset.' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 15:17:26
User opened query 'PV Query: Please provide treatment given for the event including surgical treatments (including date and name of curative surgery). 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)	25 Sep 2020 15:17:14
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)	25 Sep 2020 15:16:43
User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 15:16:06
User entered 'Patient diagnosed with colon cancer on 15Sep2020. No stage was determined and surgery has yet to be scheduled. Patient says chemotherapy is not expected and should only require surgery'	Eileen Euperio (b) (4) (b) (4)	17 Sep 2020 22:06:02

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:58:33**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Sep 2020 22:06:02

**US3342088**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:58:33**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Sep 2020 22:06:02

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 26 Nov 2020 10:58:33**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:20:16
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:15:50

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:58:33

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:21:11
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 21:04:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	02 Oct 2020 18:16:42
User entered 'influenza vaccine'	Eileen Euperio (b) (4)	02 Oct 2020 18:16:33
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:58:33

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:21:11
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:16:33

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:58:33

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:21:11
User entered 'wellness'	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:16:33



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:58:33

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:21:11
User entered '1'	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:16:33

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:58:33

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:21:11
User entered 'Other (OTHER)'	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:16:33

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:58:33**

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:21:11
User entered 'injection'	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:16:33

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:58:33

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:21:11
User entered 'once (ONCE)'	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:16:33

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:58:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:21:11
User entered empty.	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:16:33

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:58:33**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:21:11
User entered 'Intramuscular (INTRAMUSCULAR)'	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:16:33

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:58:33**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:21:11
User entered empty.	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:16:33

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:58:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:21:11
User entered '24 Sep 2020'	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:16:33



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:58:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:21:11
User entered '0'	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:16:33

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:58:33**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:21:11
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:16:33

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:58:33**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:21:11
User entered '24 Sep 2020'	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:16:33

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:58:33**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:21:11
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:16:33

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:58:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 18:16:33

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:58:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 18:16:33

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:58:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 18:16:33

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:58:33

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:21:11
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 19:05:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	14 Oct 2020 19:05:30
Data point term sent to Coder	System	14 Oct 2020 19:05:10
User entered 'Acetaminophen'	Darrell O'Brien (b) (4)	14 Oct 2020 19:04:10
	(b) (4)	



US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:58:33

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:21:11
User entered 'No (N)'	Darrell O'Brien (b) (4) (b) (4)	14 Oct 2020 19:04:10

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:58:33

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:21:11
User entered 'Post operative pain (Colonic Tumor Resection)'	Darrell O'Brien (b) (4) (b) (4)	14 Oct 2020 19:04:10

US3342088

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:58:33**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:21:11
User entered '700'	Darrell O'Brien (b) (4) (b) (4)	14 Oct 2020 19:04:10

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:58:33

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:21:11
User entered 'mg (mg)'	Darrell O'Brien (b) (4) (b) (4)	14 Oct 2020 19:04:10

US3342088

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:58:33**

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:21:11
User entered empty.	Darrell O'Brien (b) (4) (b) (4)	14 Oct 2020 19:04:10

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:58:33

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:21:11
User entered 'as needed (PRN)'	Darrell O'Brien (b) (4) (b) (4)	14 Oct 2020 19:04:10

US3342088

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:58:33**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:21:11
User entered empty.	Darrell O'Brien (b) (4) (b) (4)	14 Oct 2020 19:04:10

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:58:33

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:21:11
User entered 'Oral (ORAL)'	Darrell O'Brien (b) (4) (b) (4)	14 Oct 2020 19:04:10



US3342088

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:58:33**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:21:11
User entered empty.	Darrell O'Brien (b) (4) (b) (4)	14 Oct 2020 19:04:10

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:58:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:21:11
User entered '30 Sep 2020'	Darrell O'Brien (b) (4) (b) (4)	14 Oct 2020 19:04:10

US3342088

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:58:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:21:11
User entered '0'	Darrell O'Brien (b) (4) (b) (4)	14 Oct 2020 19:04:10

US3342088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:58:33

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:21:11
User entered 'No (N)'	Darrell O'Brien (b) (4) (b) (4)	14 Oct 2020 19:04:10

US3342088

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:58:33**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:21:11
User entered '03 Oct 2020'	Darrell O'Brien (b) (4) (b) (4)	14 Oct 2020 19:04:10

US3342088

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:58:33**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:21:11
User entered 'No (N)'	Darrell O'Brien (b) (4) (b) (4)	14 Oct 2020 19:04:10

US3342088

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:58:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 19:04:10

US3342088

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:58:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 19:04:10



US3342088

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:58:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 19:04:10

US3342088

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 26 Nov 2020 10:58:33**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:30:37
User entered 'Yes (Y)'	Darrell O'Brien (b) (4) (b) (4)	14 Oct 2020 19:08:17

US3342088

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 26 Nov 2020 10:58:33**

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:31:15
User entered '30 Sep 2020'	Darrell O'Brien (b) (4) (b) (4)	14 Oct 2020 19:09:04

US3342088

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 10:58:33

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:31:15
User entered 'Colonic Tumor Resection'	Darrell O'Brien (b) (4) (b) (4)	14 Oct 2020 19:09:04

US3342088

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 10:58:33

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:31:15
User closed query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 14:31:35
Query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification.' answered with 'Updated' (Site from DM).	Darrell O'Brien (b) (4)	05 Nov 2020 17:41:17
User opened query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 02:00:41
User closed query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	14 Oct 2020 19:09:31
User opened query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	14 Oct 2020 19:09:04
User entered 'Adverse Event (AE)'	Darrell O'Brien (b) (4)	14 Oct 2020 19:09:04

US3342088

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 26 Nov 2020 10:58:33**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:31:15
User entered empty; reason for change Data Entry Error	Darrell O'Brien (b) (4)	14 Oct 2020 19:09:31
User entered 'SAE - Stage III Colon Cancer Diagnosis'	Darrell O'Brien (b) (4)	14 Oct 2020 19:09:04

US3342088

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 26 Nov 2020 10:58:33**

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:31:15
User entered '30 Sep 2020'	Darrell O'Brien (b) (4) (b) (4)	14 Oct 2020 19:10:04

US3342088

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 26 Nov 2020 10:58:33**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:31:15
User entered 'Ileostomy'	Darrell O'Brien (b) (4) (b) (4)	14 Oct 2020 19:10:04



US3342088

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 10:58:33

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:31:15
User entered 'Adverse Event (AE)'	Darrell O'Brien (b) (4) (b) (4)	14 Oct 2020 19:10:04

US3342088

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 10:58:33

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:31:15
User entered empty.	Darrell O'Brien (b) (4) (b) (4)	14 Oct 2020 19:10:04

US3342088

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 26 Nov 2020 10:58:33**

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:31:15
User entered '16 Oct 2020'	Darrell O'Brien (b) (4) (b) (4)	05 Nov 2020 18:17:48

US3342088

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 26 Nov 2020 10:58:33**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:31:15
User entered 'MRI POWER-PORT (FOR CHEMOTHERAPY) Right subclavian.' reason for change: New Information	Darrell O'Brien (b) (4)	05 Nov 2020 19:01:41
User entered 'MRI Power-port (for chemotherapy).'	Darrell O'Brien (b) (4)	05 Nov 2020 18:17:48

US3342088

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 26 Nov 2020 10:58:33**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:31:15
User entered 'Adverse Event (AE)'	Darrell O'Brien (b) (4) (b) (4)	05 Nov 2020 18:17:48

US3342088

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 26 Nov 2020 10:58:33**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:31:15
User entered empty.	Darrell O'Brien (b) (4) (b) (4)	05 Nov 2020 18:17:48

US3342088

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (4)**

**Generated On: 26 Nov 2020 10:58:33**

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:31:15
User entered '31 Aug 2020'	Darrell O'Brien (b) (4) (b) (4)	05 Nov 2020 18:59:52

US3342088

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (4)**

**Generated On: 26 Nov 2020 10:58:33**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:31:15
User entered 'Colonoscopy'	Darrell O'Brien (b) (4) (b) (4)	05 Nov 2020 18:59:52



US3342088

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (4)**

**Generated On: 26 Nov 2020 10:58:33**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:31:15
User entered 'Diagnostic (DIAGNOSTIC)'	Darrell O'Brien (b) (4) (b) (4)	05 Nov 2020 18:59:52

US3342088

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 26 Nov 2020 10:58:33

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:31:15
User entered empty.	Darrell O'Brien (b) (4) (b) (4)	05 Nov 2020 18:59:52

US3342088

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (5)**

**Generated On: 26 Nov 2020 10:58:33**

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:31:15
User entered '31 Aug 2020'	Darrell O'Brien (b) (4) (b) (4)	05 Nov 2020 19:00:18

US3342088

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (5)**

**Generated On: 26 Nov 2020 10:58:33**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:31:15
User entered 'EGD'	Darrell O'Brien (b) (4) (b) (4)	05 Nov 2020 19:00:18

US3342088

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 26 Nov 2020 10:58:33

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:31:15
User entered 'Diagnostic (DIAGNOSTIC)'	Darrell O'Brien (b) (4) (b) (4)	05 Nov 2020 19:00:18

US3342088

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (5)**

**Generated On: 26 Nov 2020 10:58:33**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:31:15
User entered empty.	Darrell O'Brien (b) (4) (b) (4)	05 Nov 2020 19:00:18

US3342088

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (6)**

**Generated On: 26 Nov 2020 10:58:33**

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:31:15
User entered '22 Sep 2020'	Darrell O'Brien (b) (4) (b) (4)	05 Nov 2020 19:01:04

US3342088

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (6)**

**Generated On: 26 Nov 2020 10:58:33**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:31:15
User entered 'CT Scan (Chest, Abd, Pelv) with contrast'	Darrell O'Brien (b) (4) (b) (4)	05 Nov 2020 19:01:04



US3342088

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 26 Nov 2020 10:58:33

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:31:15
User entered 'Diagnostic (DIAGNOSTIC)'	Darrell O'Brien (b) (4) (b) (4)	05 Nov 2020 19:01:04

US3342088

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (6)**

**Generated On: 26 Nov 2020 10:58:33**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:31:15
User entered empty.	Darrell O'Brien (b) (4) (b) (4)	05 Nov 2020 19:01:04

US3342088

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:58:33

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '17 Sep 2020'	Eileen Euperio (b) (4) (b) (4)	25 Sep 2020 13:40:49

US3342088

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:58:33

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Primary reason for dosing discontinuation is recorded as 'SAE,However, no data is recorded on 'End of Study / Study Discontinuation' form. Kindly verify and consider to update all the necessary eCRFs required else clarify.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 14:29:51
Query 'Per CDM: Primary reason for dosing discontinuation is recorded as 'SAE,However, no data is recorded on 'End of Study / Study Discontinuation' form. Kindly verify and consider to update all the necessary eCRFs required else clarify.' answered with 'Per CRF guidelines, subject does not meet necessary criteria for study discontinuation. Subject has discontinued dosing, but is still participating in the study and attending all visits.' (Site from DM).	Ethan Shotton (b) (4)	05 Nov 2020 22:29:29
User opened query 'Per CDM: Primary reason for dosing discontinuation is recorded as 'SAE,However, no data is recorded on 'End of Study / Study Discontinuation' form. Kindly verify and consider to update all the necessary eCRFs required else clarify.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 09:34:45
User entered 'SAE (specify) (SAE)'	Eileen Euperio (b) (4)	25 Sep 2020 13:40:49

US3342088

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:58:33

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

Audit	User	Time (GMT)
User closed query 'Per CDM Re-Query: thank you for the update however, please consider recorded the record number (AE#1 or SAE#1, etc.) instead of AEID number.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 08:43:20
Query 'Per CDM Re-Query: thank you for the update however, please consider recorded the record number (AE#1 or SAE#1, etc.) instead of AEID number.' answered with 'updated' (Site from DM).	Eileen Euperio (b) (4)	23 Nov 2020 14:01:48
User entered 'AE #1' reason for change: New Information	(b) (4)	23 Nov 2020 14:01:44
User opened query 'Per CDM Re-Query: thank you for the update however, please consider recorded the record number (AE#1 or SAE#1, etc.) instead of AEID number.' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 23:34:32
User closed query 'Per CDM: please record SAE record number (i.e. SAE #1, etc.) instead of details' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 23:34:32
Query 'Per CDM: please record SAE record number (i.e. SAE #1, etc.) instead of details' answered with 'updated' (Site from DM).	Eileen Euperio (b) (4)	19 Nov 2020 23:23:32
User entered 'USA-US203-2020-MRNA-1273-P301000001' reason for change: New Information	Eileen Euperio (b) (4)	19 Nov 2020 23:23:22
User opened query 'Per CDM: please record SAE record number (i.e. SAE #1, etc.) instead of details' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 14:58:59
User entered 'colon cancer diagnosis'	Eileen Euperio (b) (4)	25 Sep 2020 13:40:49

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:58:33

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'USA-US203-2020-MRNA-1273-P301000001'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:58:33

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'Yes (Y)'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:58:33

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'No (N)'	System	18 Sep 2020 16:03:52



US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:58:33

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'No (N)'	System	18 Sep 2020 16:03:52

**US3342088**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:58:33**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'No (N)'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:58:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'No (N)'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:58:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'No (N)'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:58:33

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'Yes (Y)'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:58:33

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:10:21
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:07:57
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:45:05
User entered 'US' (non-conformant).	System	18 Sep 2020 16:04:31

**US3342088**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:58:33**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	06 Nov 2020 16:42:04
User entered '3'	System	15 Oct 2020 13:02:27
User entered '2'	System	12 Oct 2020 15:10:29
User entered '1'	System	18 Sep 2020 16:04:31

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:58:33

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'USA-US203-2020-MRNA-1273-P301000001'	System	18 Sep 2020 16:03:52



**US3342088**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:58:33**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'Yes (Y)'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:58:33

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'No (N)'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:58:33

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'No (N)'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:58:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'No (N)'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:58:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'No (N)'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:58:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'No (N)'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:58:33

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'Yes (Y)'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:58:33

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:10:21
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:07:57
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:45:05
User entered 'US' (non-conformant).	System	18 Sep 2020 16:04:31



**US3342088**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:58:33**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	06 Nov 2020 16:42:04
User entered '3'	System	15 Oct 2020 13:02:27
User entered '2'	System	12 Oct 2020 15:10:29
User entered '1'	System	18 Sep 2020 16:04:31

**US3342088**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (1)**

**Generated On: 26 Nov 2020 10:58:33**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:07:57
User entered '18/Sep/2020 12:04'	System	18 Sep 2020 16:04:31

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:58:33

**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)
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:10:21
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:07:57
User entered 'I'	(b) (4), (b) (6)	18 Sep 2020 16:04:31

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:58:33

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'USA-US203-2020-MRNA-1273-P301000001'	System	18 Sep 2020 16:03:52

**US3342088**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:58:33**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'Yes (Y)'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:58:33

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'No (N)'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:58:33

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'No (N)'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:58:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'No (N)'	System	18 Sep 2020 16:03:52



US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:58:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'No (N)'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:58:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'No (N)'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:58:33

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'Yes (Y)'	System	18 Sep 2020 16:03:52

**US3342088**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:58:33**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:10:21
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:07:57
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:45:05
User entered 'US' (non-conformant).	System	18 Sep 2020 16:04:31

**US3342088**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:58:33**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	06 Nov 2020 16:42:04
User entered '3'	System	15 Oct 2020 13:02:27
User entered '2'	System	12 Oct 2020 15:10:29
User entered '1'	System	18 Sep 2020 16:04:31

**US3342088**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (2)**

**Generated On: 26 Nov 2020 10:58:33**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 23:14:21
User entered '12/Oct/2020 11:10'	System	12 Oct 2020 15:10:29

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:58:33

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 23:14:21
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 13:02:18
User entered 'I'	(b) (4), (b) (6)	12 Oct 2020 15:10:29

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:58:33

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'USA-US203-2020-MRNA-1273-P301000001'	System	18 Sep 2020 16:03:52



US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:58:33

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'Yes (Y)'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:58:33

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'No (N)'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:58:33

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'No (N)'	System	18 Sep 2020 16:03:52

**US3342088**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:58:33**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'No (N)'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:58:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'No (N)'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:58:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'No (N)'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:58:33

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'Yes (Y)'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:58:33

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:10:21
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:07:57
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:45:05
User entered 'US' (non-conformant).	System	18 Sep 2020 16:04:31



**US3342088**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:58:33**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	06 Nov 2020 16:42:04
User entered '3'	System	15 Oct 2020 13:02:27
User entered '2'	System	12 Oct 2020 15:10:29
User entered '1'	System	18 Sep 2020 16:04:31

**US3342088**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (3)**

**Generated On: 26 Nov 2020 10:58:33**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 23:14:21
User entered '15/Oct/2020 09:02'	System	15 Oct 2020 13:02:27

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 10:58:33

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 23:14:21
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 16:41:50
User entered 'I'	(b) (4), (b) (6)	15 Oct 2020 13:02:27

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:58:33

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'USA-US203-2020-MRNA-1273-P301000001'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:58:33

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'Yes (Y)'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:58:33

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'No (N)'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:58:33

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'No (N)'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:58:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'No (N)'	System	18 Sep 2020 16:03:52



US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:58:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'No (N)'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:58:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'No (N)'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:58:33

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:07:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Sep 2020 16:04:21
User entered 'Yes (Y)'	System	18 Sep 2020 16:03:52

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:58:33

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 15:10:21
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:07:57
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:45:05
User entered 'US' (non-conformant).	System	18 Sep 2020 16:04:31

**US3342088**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:58:33**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	06 Nov 2020 16:42:04
User entered '3'	System	15 Oct 2020 13:02:27
User entered '2'	System	12 Oct 2020 15:10:29
User entered '1'	System	18 Sep 2020 16:04:31

**US3342088**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (4)**

**Generated On: 26 Nov 2020 10:58:33**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 23:14:21
User entered '06/Nov/2020 11:41'	System	06 Nov 2020 16:42:04

US3342088

Folder: SAE USA-US203-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 10:58:33

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 23:14:21
User entered 'I'	(b) (4), (b) (6)	06 Nov 2020 16:42:04