

US3022103 (Prod: Meridian Clinical Research)

Generated By: (b) (6)

Generated On: 26 Nov 2020 08:42:00

All time stamps listed in this document are displayed in GMT

**US3022103**

**Form: Participant Creation**

**Generated On: 26 Nov 2020 08:42:00**

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[Participant ID](#)

US3022103

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

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**US3022103**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 08:42:00**

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	31 JUL 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 08:42:00

Date of Birth (MMM yyyy)	(b) (6) 1960
Age	59
Age Units	YEARS
Age (Derived)	59
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 08:42:00

Date of Informed Consent ( <i>dd MMM yyyy</i> )	31 JUL 2020
Month and Year of Informed Consent (derived)	JUL 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/>
	Amendment 2 <input 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 08:42:00**

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

Yes ☒

No ☐

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**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 26 Nov 2020 08:42:00**

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:42:00

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2003
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 2003
Start Year (derived)	2003
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:42:00

Condition	BILATERAL ONYCHOMYCOSIS
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:42:00

Condition	POST MENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:42:00

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	31 JUL 2020
Time of assessment ( <i>00:00-23:59</i> )	15:05 (24 HR)
Vital Signs Date and Time (derived)	31 JUL 2020 15:05
Height ( <i>xxx.x</i> )	163.5 cm
Weight ( <i>xxx.x</i> )	63.9 kg
BMI ( <i>xxx.x</i> )	23.90371 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 08:42:00

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

31 JUL 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 08:42:00

Date of assessment ( <i>dd MMM yyyy</i> )	31 JUL 2020
Is the participant of childbearing potential?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If No, what is the reason?	Surgically sterile <input type="radio"/>
	Post-menopausal <input checked="" type="radio"/>
	Partner medically sterile <input type="radio"/>
	Not reached age of Menarche <input type="radio"/>
	Other <input type="radio"/>
If Partner medically sterile or Other, specify _____	
If Surgically sterile, date of surgery ( <i>dd MMM yyyy</i> ) _____	
Date of surgery unknown	False
If Post-menopausal, date of last menstruation ( <i>dd MMM yyyy</i> )	UN UNK 2010
Date of last menstruation unknown	False

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:42:00

**Occupational Risk**

<b>Healthcare workers</b> (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
<b>Emergency Response</b> (e.g., Law enforcement officers, Firefighters, emergency medical service workers)	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
<b>Retail or Restaurant Operations</b> , particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
<b>Manufacturing &amp; Production Operations</b> with inherent overcrowding (e.g., factory workers, meat/food processing plants)	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
<b>Warehouse shipping and fulfillment centers</b> and jobs (e.g., Amazon facilities)	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
<b>Transportation and delivery services</b> (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
<b>Border Protection and Military Personnel</b> (e.g., TSA, custom and border protection agents, military personnel not social distancing)	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
<b>Personal Care and in-home services</b> (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
<b>Hospitality and Tourism Workers</b> (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
<b>Pastoral, Social or Public Health Workers</b> requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
<b>Educators and Students</b> (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
<b>Other</b>	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

**Specify**

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

<b>No Risk Identified</b>	False
<b>Resides in Nursing Home or Assisted Living Facility</b>	False
<b>Resides in Multi-family dwelling</b> (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False

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Folder: Screening

Form: Risk of Exposure

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<b>Resides in high density housing</b> (e.g., high rise apartments with shared entrances or elevators)	False
<b>Resides in low density, multi-family setting without</b> (e.g., apartments complex without shared entrances or elevators, duplexes)	False
<b>Resides in a single family home</b> (i.e., detached housing)	True
<b>Other</b>	True
<b>Specify</b>	LIVES IN COMMUNITY WITH ONGOING PERSON TO PERSON TRANSMISSION

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 08:42:00

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	31 JUL 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 08:42:00

What was the date of randomization? (dd MMM yyyy) 31 JUL 2020

What was the participant's randomization number? 100470

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 ☒

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 26 Nov 2020 08:42:00**

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 08:42:00

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)	31 JUL 2020
Time of assessment (00:00-23:59)	15:05 (24 HR)
Vital Signs Date and Time (derived)	31 JUL 2020 15:05
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	100 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 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 08:42:00

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)	31 JUL 2020
Time of assessment (00:00-23:59)	16:56 (24 HR)
Vital Signs Date and Time (derived)	31 JUL 2020 16:56
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 08:42:00

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

31 JUL 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:42:00

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)	31 JUL 2020
What was the treatment time? (00:00-23:59)	16:20 (24 HR)
Treatment Date and Time (derived)	31 JUL 2020 16:20
Which arm was used to give treatment?	Left Arm <input checked="" type="radio"/>
	Right Arm <input 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 08:42:00

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	31 JUL 2020
Collection time ( <i>00:00-23:59</i> )	16:02 (24 HR)
Collection date and time (derived)	31 JUL 2020 16:02

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 08:42:00

Collection date ( <i>dd MMM yyyy</i> )			31 JUL 2020
Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:35	31 JUL 2020 15:35
Nasopharyngeal Swab 2	No		



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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 08:42:00

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 08:42:00

**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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 JUL 2020 16:53

PC Open Date & Time

31 JUL 2020 16:40

PC Close Date & Time

31 JUL 2020 19:10

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 08:42:00

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.7 °F

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

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

PC Time Stamp	31 JUL 2020 20:13
PC Open Date & Time	31 JUL 2020 20:05
PC Close Date & Time	01 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 08:42:00

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.2 °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

01 AUG 2020 18:28

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 08:42:00

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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

99.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 AUG 2020 19:14

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 08:42:00

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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

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

03 AUG 2020 21:39

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 08:42:00

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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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 AUG 2020 21:15

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 08:42:00

---

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

97.9 °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

05 AUG 2020 18:57

---

PC Open Date & Time

05 AUG 2020 12:00

---

PC Close Date & Time

06 AUG 2020 11:59

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US3022103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 08:42:00

---

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

96.9 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

06 AUG 2020 19:00

---

PC Open Date & Time

06 AUG 2020 12:00

---

PC Close Date & Time

07 AUG 2020 11:59

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US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 08:42:00

**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

31 JUL 2020 16:54

PC Open Date & Time

31 JUL 2020 16:40

PC Close Date & Time

31 JUL 2020 19:10

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 08:42:00

**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

31 JUL 2020 20:13

PC Open Date & Time

31 JUL 2020 20:05

PC Close Date & Time

01 AUG 2020 11:59

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 08:42:00

**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

01 AUG 2020 18:30

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 08:42:00

**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

02 AUG 2020 19:15

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 08:42:00

**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

03 AUG 2020 21:40

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 08:42:00

**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

04 AUG 2020 21:15

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 08:42:00

**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

05 AUG 2020 18:58

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59



US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 08:42:00

**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

06 AUG 2020 19:00

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3022103

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 08:42:00

**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 ☐

US3022103

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 08:42:00

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

No ☒

Yes ☐

PC Time stamp	31 JUL 2020 16:55
PC Open Date & Time	31 JUL 2020 16:40
PC Close Date & Time	31 JUL 2020 19:10

US3022103

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 08:42:00

**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 ☐

US3022103

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 08:42:00

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

No ☒

Yes ☐

PC Time stamp	31 JUL 2020 20:14
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PC Open Date & Time	31 JUL 2020 20:05
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PC Close Date & Time	01 AUG 2020 11:59
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US3022103

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 08:42:00

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 ☒

US3022103

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 08:42:00

Yes <input type="checkbox"/>	
PC Time stamp	01 AUG 2020 18:31
PC Open Date & Time	01 AUG 2020 12:00
PC Close Date & Time	02 AUG 2020 11:59

US3022103

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 08:42:00

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 ☒



US3022103

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 08:42:00

Yes <input type="checkbox"/>	
PC Time stamp	02 AUG 2020 19:15
PC Open Date & Time	02 AUG 2020 12:00
PC Close Date & Time	03 AUG 2020 11:59

US3022103

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 08:42:00

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 ☒

US3022103

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 08:42:00

Yes <input type="checkbox"/>	
PC Time stamp	03 AUG 2020 21:40
PC Open Date & Time	03 AUG 2020 12:00
PC Close Date & Time	04 AUG 2020 11:59

US3022103

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 08:42:00

**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 ☒

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 08:42:00**

Yes <input type="checkbox"/>	
PC Time stamp	04 AUG 2020 21:15
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

US3022103

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 08:42:00

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 ☒

US3022103

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 08:42:00

Yes <input type="checkbox"/>	
PC Time stamp	05 AUG 2020 18:58
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3022103

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 08:42:00

**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 ☒



US3022103

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 08:42:00

Yes <input type="checkbox"/>	
PC Time stamp	06 AUG 2020 19:01
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3022103

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:42:00

Was Contact Attempted?

Yes ☒

No ☐

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

10 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3022103

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:42:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3022103**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 08:42:00**

*Was Contact Attempted?*

Yes ☒

No ☐

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

17 AUG 2020

*Please select one status for the follow-up contact*

Contact Made ☒

Contact Not Made ☐

*Comments*

*If Contact Not Made, please provide Comments*

US3022103

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:42:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3022103**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 08:42:00**

Was Contact Attempted?

Yes ☒

No ☐

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

21 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3022103

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:42:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3022103**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 08:42:00**

Was this visit performed? Yes ☐  
No ☐

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

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

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



US3022103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:42:00

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

US3022103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:42:00

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

US3022103

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 08:42:00

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.*

US3022103

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:42:00

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 23 NOV 2020

What was the treatment time? (00:00-23:59) 12:04 (24 HR)

Treatment Date and Time (derived) 23 NOV 2020 12:04

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

What was the frequency of the study treatment dosing? ONCE

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

**US3022103**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 08:42:00**

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

**US3022103**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 26 Nov 2020 08:42:00**

Collection date ( <i>dd MMM yyyy</i> )			
Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1			
Nasopharyngeal Swab 2			

**US3022103**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 08:42:00**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 08:42:00

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 NOV 2020 12:33

PC Open Date & Time

23 NOV 2020 12:24

PC Close Date & Time

23 NOV 2020 14:54



US3022103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 08:42:00

**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 98.1 °F

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

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

PC Time Stamp	23 NOV 2020 17:46
PC Open Date & Time	23 NOV 2020 15:49
PC Close Date & Time	24 NOV 2020 11:59

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 08:42:00

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.2 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

24 NOV 2020 12:30

PC Open Date & Time

24 NOV 2020 12:00

PC Close Date & Time

25 NOV 2020 11:59

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 08:42:00

**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**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 25 NOV 2020 12:00

PC Close Date & Time 26 NOV 2020 11:59

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 08:42:00

**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**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 26 NOV 2020 12:00

PC Close Date & Time 27 NOV 2020 11:59

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 08:42:00

**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**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 27 NOV 2020 12:00

PC Close Date & Time 28 NOV 2020 11:59

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 08:42:00

**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**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 28 NOV 2020 12:00

PC Close Date & Time 29 NOV 2020 11:59

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 08:42:00

**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**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 29 NOV 2020 12:00

PC Close Date & Time 30 NOV 2020 11:59

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 08:42:00

**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

23 NOV 2020 12:34

PC Open Date & Time

23 NOV 2020 12:24

PC Close Date & Time

23 NOV 2020 14:54



US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 08:42:00

**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

23 NOV 2020 17:47

PC Open Date & Time

23 NOV 2020 15:49

PC Close Date & Time

24 NOV 2020 11:59

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 08:42:00

**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

24 NOV 2020 12:31

PC Open Date & Time

24 NOV 2020 12:00

PC Close Date & Time

25 NOV 2020 11:59

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 08:42:00

**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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

25 NOV 2020 12:00

PC Close Date & Time

26 NOV 2020 11:59

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 08:42:00

**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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

26 NOV 2020 12:00

PC Close Date & Time

27 NOV 2020 11:59

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 08:42:00

**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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

27 NOV 2020 12:00

PC Close Date & Time

28 NOV 2020 11:59

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 08:42:00

**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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

28 NOV 2020 12:00

PC Close Date & Time

29 NOV 2020 11:59

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 08:42:00

**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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

29 NOV 2020 12:00

PC Close Date & Time

30 NOV 2020 11:59

US3022103

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 08:42:00

**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 ☐



US3022103

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 08:42:00

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

No ☒

Yes ☐

PC Time stamp	23 NOV 2020 12:34
PC Open Date & Time	23 NOV 2020 12:24
PC Close Date & Time	23 NOV 2020 14:54

US3022103

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 08:42:00

**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 ☐

US3022103

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 08:42:00

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

No ☒

Yes ☐

PC Time stamp	23 NOV 2020 17:48
PC Open Date & Time	23 NOV 2020 15:49
PC Close Date & Time	24 NOV 2020 11:59

US3022103

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 08:42:00

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 ☒

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 08:42:00**

Yes <input type="checkbox"/>	
PC Time stamp	24 NOV 2020 12:32
PC Open Date & Time	24 NOV 2020 12:00
PC Close Date & Time	25 NOV 2020 11:59

US3022103

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 08:42:00

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 ☐

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 08:42:00**

		Yes <input type="checkbox"/>
<hr/>		
PC Time stamp		
<hr/>		
PC Open Date & Time		25 NOV 2020 12:00
<hr/>		
PC Close Date & Time		26 NOV 2020 11:59
<hr/>		

US3022103

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 08:42:00

**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 ☐



**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 08:42:00**

		Yes <input type="checkbox"/>
<hr/>		
PC Time stamp		
<hr/>		
PC Open Date & Time		26 NOV 2020 12:00
<hr/>		
PC Close Date & Time		27 NOV 2020 11:59
<hr/>		

US3022103

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 08:42:00

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 ☐

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 08:42:00**

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

US3022103

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 08:42:00

**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 ☐

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 08:42:00**

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

US3022103

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 08:42:00

**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 ☐

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 08:42:00**

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

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	01 OCT 2020 14:28:43
Patient Cloud Open Date & Time	30 SEP 2020 00:01
Patient Cloud Close Date & Time	04 OCT 2020 23:59



US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

**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

14 OCT 2020 11:43:13

Patient Cloud Open Date & Time

14 OCT 2020 00:01

Patient Cloud Close Date & Time

18 OCT 2020 23:59

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

**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

31 OCT 2020 18:56:20

Patient Cloud Open Date & Time

28 OCT 2020 00:01

Patient Cloud Close Date & Time

01 NOV 2020 23:59

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

**TIMEPOINT**

DAY 99

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 NOV 2020 12:04:03

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

**TIMEPOINT**

DAY 106

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 NOV 2020 00:01:41

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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="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"/>

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2020 00:01

[Patient Cloud Close Date & Time](#)

01 OCT 2020 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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"/>

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

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[Patient Cloud Close Date & Time](#)

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08 OCT 2020 23:59

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US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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="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"/>

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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="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"/>

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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="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"/>

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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="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"/>

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

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[Patient Cloud Close Date & Time](#)

05 NOV 2020 23:59

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US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

**TIMEPOINT**

DAY 103

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

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

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

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

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[Patient Cloud Close Date & Time](#)

12 NOV 2020 23:59

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US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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"/>

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 NOV 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 NOV 2020 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 NOV 2020 22:18:08

Patient Cloud Open Date & Time

22 NOV 2020 00:01

Patient Cloud Close Date & Time

26 NOV 2020 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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"/>

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

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[Patient Cloud Close Date & Time](#)

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03 DEC 2020 23:59

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US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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="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"/>



**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	06 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	10 DEC 2020 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

**TIMEPOINT**

DAY 138

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

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

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

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 DEC 2020 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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="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"/>

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 DEC 2020 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

**TIMEPOINT**

DAY 152

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

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

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

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 DEC 2020 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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="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"/>



**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

**TIMEPOINT**

DAY 173

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

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

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

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

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

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

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

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

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

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[Patient Cloud Close Date & Time](#)

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21 JAN 2021 23:59

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US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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="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"/>

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

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[Patient Cloud Close Date & Time](#)

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28 JAN 2021 23:59

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US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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="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"/>



**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

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[Patient Cloud Close Date & Time](#)

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04 FEB 2021 23:59

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US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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="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"/>

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

[Patient Cloud Open Date & Time](#)

07 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

11 FEB 2021 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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"/>

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

18 FEB 2021 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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"/>



**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

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[Patient Cloud Close Date & Time](#)

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04 MAR 2021 23:59

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US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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"/>

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

07 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 MAR 2021 23:59

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US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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"/>

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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"/>

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

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[Patient Cloud Close Date & Time](#)

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25 MAR 2021 23:59

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US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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"/>



**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

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[Patient Cloud Close Date & Time](#)

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01 APR 2021 23:59

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US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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="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"/>

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	04 APR 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	08 APR 2021 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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"/>

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

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[Patient Cloud Close Date & Time](#)

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22 APR 2021 23:59

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US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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"/>



**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

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[Patient Cloud Close Date & Time](#)

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06 MAY 2021 23:59

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US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

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[Patient Cloud Close Date & Time](#)

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13 MAY 2021 23:59

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US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 MAY 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 MAY 2021 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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="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"/>



**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

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[Patient Cloud Close Date & Time](#)

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27 MAY 2021 23:59

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US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

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[Patient Cloud Close Date & Time](#)

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03 JUN 2021 23:59

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US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

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[Patient Cloud Close Date & Time](#)

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10 JUN 2021 23:59

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US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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="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"/>

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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="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"/>



**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

**TIMEPOINT**

DAY 334

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

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

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

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

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

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

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

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

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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"/>

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	04 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	08 JUL 2021 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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 ☐



**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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"/>

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

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[Patient Cloud Close Date & Time](#)

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05 AUG 2021 23:59

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US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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 ☐  
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 ☐

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

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[Patient Cloud Open Date & Time](#)

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08 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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12 AUG 2021 23:59

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US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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"/>



**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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"/>

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

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[Patient Cloud Close Date & Time](#)

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02 SEP 2021 23:59

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US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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"/>

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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="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"/>



**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

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[Patient Cloud Open Date & Time](#)

12 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

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US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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="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"/>

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

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[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

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US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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="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"/>



**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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"/>

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

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

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

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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"/>

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

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[Patient Cloud Close Date & Time](#)

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04 NOV 2021 23:59

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US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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



**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

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[Patient Cloud Close Date & Time](#)

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11 NOV 2021 23:59

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US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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"/>

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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="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"/>

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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"/>

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

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[Patient Cloud Close Date & Time](#)

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02 DEC 2021 23:59

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US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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



**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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 ☐

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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 ☐

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	26 DEC 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	30 DEC 2021 23:59
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US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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 ☐



**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

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[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

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US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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="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"/>

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

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[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

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US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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 ☐

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 JAN 2022 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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"/>

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

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[Patient Cloud Close Date & Time](#)

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27 JAN 2022 23:59

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US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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 ☐



**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

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[Patient Cloud Close Date & Time](#)

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03 FEB 2022 23:59

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US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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 ☐

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	06 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	10 FEB 2022 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

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

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

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

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[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

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US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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 ☐

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 FEB 2022 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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 ☐



**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

[Patient Cloud Open Date & Time](#)

27 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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 ☐

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

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[Patient Cloud Close Date & Time](#)

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10 MAR 2022 23:59

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US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

**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 ☐

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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"/>

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 MAR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 MAR 2022 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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



**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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"/>

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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"/>



**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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="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"/>

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

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[Patient Cloud Close Date & Time](#)

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05 MAY 2022 23:59

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US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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 ☐ 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 ☐

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

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[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

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US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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"/>

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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15 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 MAY 2022 23:59

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US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

**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 ☐



**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

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[Patient Cloud Close Date & Time](#)

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26 MAY 2022 23:59

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US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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"/>

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

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[Patient Cloud Close Date & Time](#)

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02 JUN 2022 23:59

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US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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 ☐

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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"/>



**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

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[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

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US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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"/>

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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"/>

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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"/>

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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"/>



**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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"/>

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

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[Patient Cloud Close Date & Time](#)

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11 AUG 2022 23:59

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US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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"/>



**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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"/>

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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"/>

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

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[Patient Cloud Close Date & Time](#)

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01 SEP 2022 23:59

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US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

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[Patient Cloud Close Date & Time](#)

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08 SEP 2022 23:59

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US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

TIMEPOINT

DAY 775

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

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

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

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

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

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

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

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



**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

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

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

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

TIMEPOINT

DAY 789

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

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

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

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

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

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

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

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

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	25 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 SEP 2022 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:42:00

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

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	02 OCT 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	06 OCT 2022 23:59
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**US3022103**

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

**Form: COVID-19 Contact**

**Generated On: 26 Nov 2020 08:42:00**

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"/>



**US3022103**

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

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

**Generated On: 26 Nov 2020 08:42:00**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

**US3022103**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 26 Nov 2020 08:42:00**

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

**If Yes, enter details on the Adverse Events form.**

---

US3022103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:42:00

AEID	
Adverse event	NECK PAIN
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)	14 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	17 AUG 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False
v6.020 DTW (1102)	322 of 1561

US3022103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:42:00

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

US3022103

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:42:00

AEID	
Adverse event	ELEVATED LIVER ENZYMES
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)	17 AUG 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 type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:42:00

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

US3022103

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:00

AEID	USA-US051-2020-MRNA-1273-P30 1000004
Adverse event	INTERMITTENT EPIGASTRIC PAIN
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)	16 AUG 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 type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	16 AUG 2020
Hospital Discharge Date (dd MMM yyyy)	17 AUG 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

v6.020 DTW (1102)

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:00

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



US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 08:42:00

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

Yes ☒

No ☐

---

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

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US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:42:00

Name of Medication	FLUTICASONE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	SEASONAL ALLERGIES
Dose per administration	50
Dose unit	mg <input type="radio"/> ug <input checked="" 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 type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input checked="" 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 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 type="radio"/>

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:42:00

Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input checked="" type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	UN UNK 2003
Start date completely unknown	False
Ongoing?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____	
Was this medication taken for solicited event?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 <input type="checkbox"/> 803 <input type="checkbox"/> 804 <input checked="" type="checkbox"/>

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:42:00

Name of Medication	KETOCONAZOLE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	ONYCHOMYCOSIS BILATERAL
Dose per administration	200-400
Dose unit	mg <input checked="" 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 type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" 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 type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="radio"/> Topical <input checked="" type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:42:00

	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 <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)	UN	UNK 2018
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <input type="text"/>		
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:42:00

Name of Medication	SUCRALFATE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	ABDOMINAL PAIN
Dose per administration	1
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input checked="" type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" 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 type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:42:00

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)	16 AUG 2020
Start date completely unknown	False
Ongoing?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____	
Was this medication taken for solicited event?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 <input type="radio"/>
	803 <input type="radio"/>
	804 <input checked="" type="radio"/>

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:42:00

Name of Medication	PANTOPRAZOLE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	ABDOMINAL PAIN
Dose per administration	40
Dose unit	mg <input checked="" 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 type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" 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 type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>



US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:42:00

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)	16 AUG 2020
Start date completely unknown	False
Ongoing?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____	
Was this medication taken for solicited event?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 <input type="radio"/>
	803 <input type="radio"/>
	804 <input checked="" type="radio"/>

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:42:00

Name of Medication	ADVIL
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	NECK PAIN
Dose per administration	400
Dose unit	mg <input checked="" 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 type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input checked="" 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 type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:42:00

	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)		15 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		16 AUG 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3022103

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 08:42:00

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3022103

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 08:42:00

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Date of dosing discontinuation (dd MMM yyyy)

---

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

---

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

---

US3022103

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 08:42:00

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 ☐

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 08:42:00

SAEID	USA-US051-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 08:42:00

SAEID	USA-US051-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	15/SEP/2020 10:48
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True



US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 08:42:00

SAEID	USA-US051-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	05/OCT/2020 08:54
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

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 08:42:00

SAEID	USA-US051-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	23/OCT/2020 20:35
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

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 08:42:00

SAEID	USA-US051-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	10/NOV/2020 17:29
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

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 08:42:00

SAEID	USA-US051-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	24/NOV/2020 07:38
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

US3022103 (Prod: Meridian Clinical Research)

**US3022103**

**Form: Participant Creation**

**Generated On: 26 Nov 2020 08:42:00**

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3022103'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	31 Jul 2020 18:49:18

**US3022103**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 08:42:00**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	31 Jul 2020 20:25:56

**US3022103**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
User entered '31 JUL 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	31 Jul 2020 18:49:19



**US3022103**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Shanice Bennett (b) (4) (b) (4)	31 Jul 2020 20:25:56

**US3022103**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 08:42:00**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	31 Jul 2020 20:25:56

**US3022103**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 08:42:00**

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered (b) (6) 1960'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	31 Jul 2020 18:49:19

**US3022103**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 08:42:00**

[Age](#)

Audit	User	Time (GMT)
User entered '59'	Shanice Bennett (b) (4) (b) (4)	31 Jul 2020 20:26:15

**US3022103**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 08:42:00**

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	31 Jul 2020 20:26:15

**US3022103**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 08:42:00**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '59'	System	31 Jul 2020 20:26:35

**US3022103**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 08:42:00**

[Sex](#)

Audit	User	Time (GMT)
User entered 'Female (F)'	Shanice Bennett (b) (4) (b) (4)	31 Jul 2020 20:26:15

**US3022103**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 08:42:00**

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Shanice Bennett (b) (4) (b) (4)	31 Jul 2020 20:26:15



**US3022103**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 08:42:00**

[White](#)

Audit	User	Time (GMT)
User entered 'I'	Shanice Bennett (b) (4) (b) (4)	31 Jul 2020 20:26:15

**US3022103**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 08:42:00**

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Shanice Bennett (b) (4) (b) (4)	31 Jul 2020 20:26:15

**US3022103**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 08:42:00**

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Shanice Bennett (b) (4) (b) (4)	31 Jul 2020 20:26:15

**US3022103**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 08:42:00**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Shanice Bennett (b) (4) (b) (4)	31 Jul 2020 20:26:15

**US3022103**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 08:42:00**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Shanice Bennett (b) (4) (b) (4)	31 Jul 2020 20:26:15

**US3022103**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 08:42:00**

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Shanice Bennett (b) (4) (b) (4)	31 Jul 2020 20:26:15

**US3022103**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 08:42:00**

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	31 Jul 2020 20:26:15

**US3022103**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 08:42:00**

[Unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shanice Bennett (b) (4) (b) (4)	31 Jul 2020 20:26:15



**US3022103**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 08:42:00**

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Shanice Bennett (b) (4) (b) (4)	31 Jul 2020 20:26:15

US3022103

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:42:00

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '31 Jul 2020'	Shanice Bennett (b) (4) (b) (4)	31 Jul 2020 20:26:35

**US3022103**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
User entered 'Jul 2020'	System	31 Jul 2020 20:26:35

**US3022103**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
User entered '2020'	System	31 Jul 2020 20:26:35

**US3022103**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 08:42:00**

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 1 (1)'	Shanice Bennett (b) (4) (b) (4)	31 Jul 2020 20:26:35

**US3022103**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	31 Jul 2020 20:26:35

**US3022103**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	31 Jul 2020 20:26:35

**US3022103**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 08:42:00**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	31 Jul 2020 20:26:35



**US3022103**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 08:42:00**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	31 Jul 2020 20:26:35

**US3022103**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 08:42:00**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	31 Jul 2020 18:49:19

**US3022103**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 08:42:00**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Jul 2020 20:26:41

**US3022103**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	31 Jul 2020 20:26:41

**US3022103**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 26 Nov 2020 08:42:00**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:05:13

US3022103

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:42:00

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	31 Jul 2020 21:07:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Jul 2020 21:07:15
Data point term sent to Coder	System	31 Jul 2020 21:05:57
User entered 'seasonal allergies'	Stella Yoon (b) (4)	31 Jul 2020 21:05:29
	(b) (4)	

**US3022103**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
User entered 'un UNK 2003'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:05:29

**US3022103**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 08:42:00**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:05:29



**US3022103**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 08:42:00**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:05:29

**US3022103**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
User entered empty.	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:05:29

**US3022103**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 08:42:00**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:05:29

**US3022103**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
User entered 'Jan 2003'	System	31 Jul 2020 21:05:29

**US3022103**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
User entered '2003'	System	31 Jul 2020 21:05:29

**US3022103**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
User entered empty.	System	31 Jul 2020 21:05:29

**US3022103**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
User entered empty.	System	31 Jul 2020 21:05:29

US3022103

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:42:00

Condition

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review and reflect if this involves the Left, Right or Bilateral EAR. Update Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 09:48:27
User coded data point as SOC: Infections and infestations, HLGT: Fungal infectious disorders, HLT: Fungal infections NEC, PT: Onychomycosis, LLT: Onychomycosis - version MedDRA\23.0.	Coder Import (b) (4)	31 Aug 2020 14:08:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	31 Aug 2020 14:08:48
Data point term sent to Coder	System	31 Aug 2020 13:16:57
Query 'Per DM CLR: Please review and reflect if this involves the Left, Right or Bilateral EAR. Update Med History eCRF as appropriate. ' answered with 'updated' (Site from DM).	Stella Yoon (b) (4)	31 Aug 2020 13:16:26
Coding entries removed.	Stella Yoon (b) (4)	31 Aug 2020 13:16:18
User entered 'bilateral onychomycosis' reason for change: Data Entry Error	Stella Yoon (b) (4)	31 Aug 2020 13:16:18
User opened query 'Per DM CLR: Please review and reflect if this involves the Left, Right or Bilateral EAR. Update Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 09:16:01
User coded data point as SOC: Infections and infestations, HLGT: Fungal infectious disorders, HLT: Fungal infections NEC, PT: Ear infection fungal, LLT: Ear infection fungal - version MedDRA\23.0.	Coder Import (b) (4)	03 Aug 2020 17:04:11
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	03 Aug 2020 17:04:11
Data point term sent to Coder	System	31 Jul 2020 21:05:58
User entered 'otomycosis'	Stella Yoon (b) (4)	31 Jul 2020 21:05:54



**US3022103**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
User entered 'un UNK 2018'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:05:54

**US3022103**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 08:42:00**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:05:54

**US3022103**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 08:42:00**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:05:54

**US3022103**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
User entered empty.	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:05:54

**US3022103**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 08:42:00**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:05:54

**US3022103**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	31 Jul 2020 21:05:54

**US3022103**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
User entered '2018'	System	31 Jul 2020 21:05:54

**US3022103**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
User entered empty.	System	31 Jul 2020 21:05:54



**US3022103**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
User entered empty.	System	31 Jul 2020 21:05:54

US3022103

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:42:00

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 13:08:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	31 Aug 2020 13:08:54
Data point term sent to Coder	System	31 Aug 2020 13:07:35
User entered 'post menopausal'	Stella Yoon (b) (4)	31 Aug 2020 13:06:58
	(b) (4)	

**US3022103**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
User entered 'un UNK 2010'	Stella Yoon (b) (4) (b) (4)	31 Aug 2020 13:06:58

**US3022103**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 08:42:00**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	31 Aug 2020 13:06:58

**US3022103**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 08:42:00**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	31 Aug 2020 13:06:58

**US3022103**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
User entered empty.	Stella Yoon (b) (4) (b) (4)	31 Aug 2020 13:06:58

**US3022103**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 08:42:00**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	31 Aug 2020 13:06:58

**US3022103**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	31 Aug 2020 13:06:58



**US3022103**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
User entered '2010'	System	31 Aug 2020 13:06:58

**US3022103**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 13:06:58

**US3022103**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 13:06:58

**US3022103**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:42:00**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:06:32

**US3022103**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:42:00**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '31 Jul 2020'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:06:32

**US3022103**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
User entered '15:05'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:06:32

**US3022103**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
User entered '31 Jul 2020 15:05'	System	31 Jul 2020 21:06:32

**US3022103**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
User entered '163.5' cm	Stella Yoon (b) (4)	31 Jul 2020 21:06:32
DataPoint set to visible.	(b) (4) System	31 Jul 2020 20:26:41



**US3022103**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
User entered '63.9' kg	Stella Yoon (b) (4)	31 Jul 2020 21:06:32
DataPoint set to visible.	(b) (4) System	31 Jul 2020 20:26:41

**US3022103**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:42:00**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Amendment Manager: User entered '23.90371'	System	16 Sep 2020 23:39:55
User entered '23.9'	System	31 Jul 2020 21:06:32
DataPoint set to visible.	System	31 Jul 2020 20:26:41

**US3022103**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:42:00**

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	31 Jul 2020 21:06:32
DataPoint set to visible.	System	31 Jul 2020 20:26:41

US3022103

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:42:00

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for “Not done” and not left empty). Please note that when ND is recorded the units should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 02:01:01
Query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for “Not done” and not left empty). Please note that when ND is recorded the units should not remain. Please review and update as appropriate. ' answered with 'UPDATED' (Site from DM).	Morgan Deal (b) (4) (b) (4)	03 Nov 2020 16:51:49
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4) (b) (4)	03 Nov 2020 16:51:38
User opened query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for “Not done” and not left empty). Please note that when ND is recorded the units should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 09:35:26
User entered '98.5' F	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:06:32

**US3022103**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:42:00**

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty; reason for change Per Query Resolution	Morgan Deal (b) (4)	03 Nov 2020 16:51:38
User entered 'Oral (Oral)'	(b) (4)	
	Stella Yoon (b) (4)	31 Jul 2020 21:06:32
	(b) (4)	

**US3022103**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:42:00**

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:06:32

**US3022103**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:42:00**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	03 Nov 2020 16:51:38
User entered '72'	(b) (4)	
	Stella Yoon (b) (4)	31 Jul 2020 21:06:32
	(b) (4)	

**US3022103**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:42:00**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	31 Jul 2020 21:06:32



US3022103

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:42:00

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	03 Nov 2020 16:51:38
User entered '14'	(b) (4)	
	Stella Yoon (b) (4)	31 Jul 2020 21:06:32
	(b) (4)	

**US3022103**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:42:00**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	31 Jul 2020 21:06:32

US3022103

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:42:00

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	03 Nov 2020 16:51:38
User entered '100'	(b) (4)	
	Stella Yoon (b) (4)	31 Jul 2020 21:06:32
	(b) (4)	

**US3022103**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:42:00**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	31 Jul 2020 21:06:32

US3022103

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:42:00

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	03 Nov 2020 16:51:38
User entered '70'	(b) (4)	
	Stella Yoon (b) (4)	31 Jul 2020 21:06:32
	(b) (4)	

**US3022103**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:42:00**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	31 Jul 2020 21:06:32

**US3022103**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 08:42:00**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:06:40

**US3022103**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 08:42:00**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
User entered '31 Jul 2020'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:06:40



**US3022103**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 08:42:00**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '31 Jul 2020'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:06:55

**US3022103**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 08:42:00**

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:06:55

US3022103

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 08:42:00

If No, what is the reason?

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 09:31:30
Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate.' answered with 'updated' (Site from DM).	Stella Yoon (b) (4)	31 Aug 2020 13:07:16
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Aug 2020 12:27:03
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Stella Yoon (b) (4)	31 Jul 2020 21:06:55

**US3022103**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 08:42:00**

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:06:55

**US3022103**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
User entered empty.	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:06:55

**US3022103**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 08:42:00**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:06:55

US3022103

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 08:42:00

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

Audit	User	Time (GMT)
User entered 'un UNK 2010'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:06:55

**US3022103**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 26 Nov 2020 08:42:00**

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:06:55



US3022103

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:42:00

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:07:25

US3022103

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:42:00

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:07:25

US3022103

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:42:00

**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)'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:07:25

**US3022103**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:07:25

US3022103

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:42:00

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:07:25

US3022103

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:42:00

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:07:25

US3022103

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:42:00

**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)'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:07:25

**US3022103**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 08:42:00**

**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)'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:07:25



US3022103

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:42:00

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:07:25

US3022103

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:42:00

**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 'No (N)'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:07:25

**US3022103**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:07:25

**US3022103**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 08:42:00**

**Other**

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:07:25

US3022103

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:42:00

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:07:25

**US3022103**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 08:42:00**

**No Risk Identified**

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:07:25

US3022103

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:42:00

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

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:07:25

**US3022103**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 08:42:00**

**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 '0'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:07:25



US3022103

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:42:00

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

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:07:25

US3022103

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:42:00

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'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:07:25

US3022103

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:42:00

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

Audit	User	Time (GMT)
User entered 'I'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:07:25

**US3022103**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 08:42:00**

**Other**

Audit	User	Time (GMT)
User entered 'I'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:07:25

US3022103

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:42:00

[Specify](#)

Audit	User	Time (GMT)
User entered 'Lives in community with ongoing person to person transmission'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:07:25

**US3022103**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 26 Nov 2020 08:42:00**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:07:36

**US3022103**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
User entered '31 Jul 2020'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:07:36

**US3022103**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:07:36



**US3022103**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 26 Nov 2020 08:42:00**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	31 Jul 2020 21:07:36

US3022103

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:42:00

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

Audit	User	Time (GMT)
User entered '31 JUL 2020'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	31 Jul 2020 20:14:15

US3022103

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:42:00

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 01:32:32
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:32:32
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	31 Jul 2020 20:14:15
User entered '100470' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	31 Jul 2020 20:14:15

US3022103

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:42:00

[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) [REDACTED]	31 Jul 2020 20:14:15

**US3022103**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 26 Nov 2020 08:42:00**

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)'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:07:50

**US3022103**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:07:50

**US3022103**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:07:50

**US3022103**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 26 Nov 2020 08:42:00**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:07:50



**US3022103**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 26 Nov 2020 08:42:00**

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:07:50

US3022103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:42:00

Height

Audit	User	Time (GMT)
User closed query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 02:01:17
Query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' answered with 'UPDATED' (Site from DM).	Morgan Deal (b) (4)	03 Nov 2020 16:47:43
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	03 Nov 2020 16:47:33
User opened query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 08:57:20
User entered '163.5' cm	Stella Yoon (b) (4)	31 Jul 2020 21:09:11

US3022103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:42:00

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	03 Nov 2020 16:47:33
User entered '63.9' kg	(b) (4)	
	Stella Yoon (b) (4)	31 Jul 2020 21:09:11
	(b) (4)	

US3022103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:42:00

Height

Audit	User	Time (GMT)
User closed query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 02:01:17
Query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' answered with 'UPDATED' (Site from DM).	Morgan Deal (b) (4)	03 Nov 2020 16:47:43
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	03 Nov 2020 16:47:33
User opened query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 08:57:20
User entered '163.5' cm	Stella Yoon (b) (4)	31 Jul 2020 21:09:11

US3022103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:42:00

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	03 Nov 2020 16:47:33
User entered '63.9' kg	(b) (4)	
	Stella Yoon (b) (4)	31 Jul 2020 21:09:11
	(b) (4)	

US3022103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:42:00

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:11

**US3022103**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 08:42:00**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:11

US3022103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:42:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '31 Jul 2020'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:11



**US3022103**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
User entered '15:05'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:11

**US3022103**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
User entered '31 Jul 2020 15:05'	System	31 Jul 2020 21:09:11

**US3022103**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 08:42:00**

**Temperature (xxx.x)**

Audit	User	Time (GMT)
User entered '98.5' F	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:11

**US3022103**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 08:42:00**

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:11

**US3022103**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 08:42:00**

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:11

US3022103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:42:00

Pulse (xxx)

Audit	User	Time (GMT)
User entered '72'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:11

**US3022103**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 08:42:00**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	31 Jul 2020 21:09:11

US3022103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:42:00

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

Audit	User	Time (GMT)
User entered '14'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:11



**US3022103**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 08:42:00**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	31 Jul 2020 21:09:11

US3022103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:42:00

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '100'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:11

**US3022103**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 08:42:00**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	31 Jul 2020 21:09:11

US3022103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:42:00

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '70'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:11

**US3022103**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 08:42:00**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	31 Jul 2020 21:09:11

US3022103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:42:00

Height

Audit	User	Time (GMT)
User closed query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 02:01:17
Query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' answered with 'UPDATED' (Site from DM).	Morgan Deal (b) (4)	03 Nov 2020 16:47:43
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	03 Nov 2020 16:47:33
User opened query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 08:57:20
User entered '163.5' cm	Stella Yoon (b) (4)	31 Jul 2020 21:09:11

US3022103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:42:00

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	03 Nov 2020 16:47:33
User entered '63.9' kg	(b) (4)	
	Stella Yoon (b) (4)	31 Jul 2020 21:09:11
	(b) (4)	

US3022103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:42:00

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:11



US3022103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:42:00

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:11

US3022103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:42:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '31 Jul 2020'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:11

US3022103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:42:00

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

Audit	User	Time (GMT)
User closed 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).	(b) (4), (b) (6)	05 Aug 2020 16:41:28
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'per protocol, 30 minutes post dose' (Site from System).	Stella Yoon (b) (4)	31 Jul 2020 21:09:19
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).	(b) (4)	31 Jul 2020 21:09:11
User entered '16:56'	Stella Yoon (b) (4)	31 Jul 2020 21:09:11

**US3022103**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
User entered '31 Jul 2020 16:56'	System	31 Jul 2020 21:09:11

US3022103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:42:00

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.7' C	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:11

**US3022103**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 08:42:00**

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:11

**US3022103**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 08:42:00**

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:11

**US3022103**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 08:42:00**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '72'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:11



**US3022103**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 08:42:00**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	31 Jul 2020 21:09:11

US3022103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:42:00

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

Audit	User	Time (GMT)
User entered '14'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:11

**US3022103**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 08:42:00**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	31 Jul 2020 21:09:11

US3022103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:42:00

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '108'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:11

**US3022103**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 08:42:00**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	31 Jul 2020 21:09:11

US3022103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:42:00

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '70'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:11

**US3022103**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 08:42:00**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	31 Jul 2020 21:09:11

**US3022103**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 08:42:00**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:27



**US3022103**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 08:42:00**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
User entered '31 Jul 2020'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:27

**US3022103**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 08:42:00**

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	31 Jul 2020 20:27:08

US3022103

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:42:00

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	31 Jul 2020 20:27:08

US3022103

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:42:00

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

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	31 Jul 2020 20:27:08

**US3022103**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 08:42:00**

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	31 Jul 2020 20:27:08

US3022103

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:42:00

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '31 Jul 2020'	Shanice Bennett (b) (4) (b) (4)	31 Jul 2020 20:27:08

US3022103

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:42:00

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

Audit	User	Time (GMT)
User entered '16:20'	Shanice Bennett (b) (4) (b) (4)	31 Jul 2020 20:27:08

**US3022103**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
User entered '31 Jul 2020 16:20'	System	31 Jul 2020 20:27:08



US3022103

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:42:00

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Shanice Bennett (b) (4) (b) (4)	31 Jul 2020 20:27:08

**US3022103**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 08:42:00**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 08:42:00**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:47

US3022103

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:42:00

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '31 Jul 2020'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:47

**US3022103**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 08:42:00**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '16:02'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:47

**US3022103**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
User entered '31 Jul 2020 16:02'	System	31 Jul 2020 21:09:47

**US3022103**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 26 Nov 2020 08:42:00**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '31 Jul 2020'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:57



**US3022103**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 08:42:00**

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:57

**US3022103**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 08:42:00**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:57

**US3022103**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
User entered '15:35'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:57

**US3022103**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
User entered '31 Jul 2020 15:35'	System	31 Jul 2020 21:09:57

**US3022103**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 08:42:00**

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:57

**US3022103**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 08:42:00**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:57

**US3022103**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
User entered empty.	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:57

**US3022103**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
User entered empty.	System	31 Jul 2020 21:09:57



US3022103

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 08:42:00

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:10:01

**US3022103**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 26 Nov 2020 08:42:00**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	31 Jul 2020 21:10:01

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	31 Jul 2020 20:27:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 08:42:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T16:53:38', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '0984129c-cd0b-4de6-87a0-37598747686b'	System	31 Jul 2020 20:53:59
User entered 'Yes (Y)'	System	31 Jul 2020 20:53:59

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 08:42:00**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T16:53:46', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '0984129c-cd0b-4de6-87a0-37598747686b'	System	31 Jul 2020 20:53:59
User entered '98.1'	System	31 Jul 2020 20:53:59

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 08:42:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T16:53:50', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '0984129c-cd0b-4de6-87a0-37598747686b'	System	31 Jul 2020 20:53:59
User entered 'No (N)'	System	31 Jul 2020 20:53:59

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T16:53:56', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '0984129c-cd0b-4de6-87a0-37598747686b'	System	31 Jul 2020 20:53:59
User entered '31 Jul 2020 16:53'	System	31 Jul 2020 20:53:59

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Jul 2020 16:40'	System	31 Jul 2020 20:27:08



**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Jul 2020 19:10'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	31 Jul 2020 20:27:08
User entered 'Day 1, after vaccination (at home)'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 08:42:00**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T20:13:23', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '6d7bbffb-ad23-4472-85a5-b5df512c66ed'	System	01 Aug 2020 00:13:39
User entered 'Yes (Y)'	System	01 Aug 2020 00:13:39

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 08:42:00**

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T20:13:30', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '6d7bbffb-ad23-4472-85a5-b5df512c66ed'	System	01 Aug 2020 00:13:39
User entered '97.7'	System	01 Aug 2020 00:13:39

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 08:42:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T20:13:33', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '6d7bbffb-ad23-4472-85a5-b5df512c66ed'	System	01 Aug 2020 00:13:39
User entered 'No (N)'	System	01 Aug 2020 00:13:39

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T20:13:37', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '6d7bbffb-ad23-4472-85a5-b5df512c66ed' User entered '31 Jul 2020 20:13'	System	01 Aug 2020 00:13:39
	System	01 Aug 2020 00:13:39

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Jul 2020 20:05'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 11:59'	System	31 Jul 2020 20:27:08



**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	31 Jul 2020 20:27:08
User entered 'Day 2'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 08:42:00**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-01T18:26:40', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'da81f6a1-157c-4669-bfd6-2ec3c41fe2a1'	System	01 Aug 2020 22:28:41
User entered 'Yes (Y)'	System	01 Aug 2020 22:28:41

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 08:42:00**

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-01T18:28:30', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'da81f6a1-157c-4669-bfd6-2ec3c41fe2a1'	System	01 Aug 2020 22:28:41
User entered '99.2'	System	01 Aug 2020 22:28:41

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 08:42:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-01T18:28:34', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'da81f6a1-157c-4669-bfd6-2ec3c41fe2a1'	System	01 Aug 2020 22:28:41
User entered 'No (N)'	System	01 Aug 2020 22:28:41

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-01T18:28:40', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'da81f6a1-157c-4669-bfd6-2ec3c41fe2a1'	System	01 Aug 2020 22:28:41
User entered '01 Aug 2020 18:28'	System	01 Aug 2020 22:28:41

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 12:00'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 11:59'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	31 Jul 2020 20:27:08
User entered 'Day 3'	System	31 Jul 2020 20:27:08



**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 08:42:00**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-02T19:12:16', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'ace41f4d-6675-457f-99d7-487fcb62cffc'	System	02 Aug 2020 23:14:54
User entered 'Yes (Y)'	System	02 Aug 2020 23:14:54

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 08:42:00**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-02T19:13:25', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'ace41f4d-6675-457f-99d7-487fcb62cffc' User entered '99.1'	System	02 Aug 2020 23:14:54

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 08:42:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-02T19:14:42', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'ace41f4d-6675-457f-99d7-487fcb62cffc'	System	02 Aug 2020 23:14:54
User entered 'No (N)'	System	02 Aug 2020 23:14:54

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-02T19:14:52', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'ace41f4d-6675-457f-99d7-487fcb62cffc'	System	02 Aug 2020 23:14:54
User entered '02 Aug 2020 19:14'	System	02 Aug 2020 23:14:54

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 12:00'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 11:59'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	31 Jul 2020 20:27:08
User entered 'Day 4'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 08:42:00**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-03T21:39:44', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '6f642f53-8580-4f71-a4e1-036e2efbe059'	System	04 Aug 2020 01:40:00
User entered 'Yes (Y)'	System	04 Aug 2020 01:40:00



**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 08:42:00**

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-03T21:39:49', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '6f642f53-8580-4f71-a4e1-036e2efbe059'	System	04 Aug 2020 01:40:00
User entered '97.4'	System	04 Aug 2020 01:40:00

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-03T21:39:52', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '6f642f53-8580-4f71-a4e1-036e2efbe059'	System	04 Aug 2020 01:40:00
User entered 'No (N)'	System	04 Aug 2020 01:40:00

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-03T21:39:56', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '6f642f53-8580-4f71-a4e1-036e2efbe059'	System	04 Aug 2020 01:40:00
User entered '03 Aug 2020 21:39'	System	04 Aug 2020 01:40:00

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 12:00'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 11:59'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	31 Jul 2020 20:27:08
User entered 'Day 5'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 08:42:00**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-04T21:13:48', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '1a690d61-2750-4fb3-8611-2c87f554858c'	System	05 Aug 2020 01:15:05
User entered 'Yes (Y)'	System	05 Aug 2020 01:15:05

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 08:42:00**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-04T21:14:57', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '1a690d61-2750-4fb3-8611-2c87f554858c'	System	05 Aug 2020 01:15:05
User entered '98.0'	System	05 Aug 2020 01:15:05



US3022103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 08:42:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-04T21:14:31', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '1a690d61-2750-4fb3-8611-2c87f554858c'	System	05 Aug 2020 01:15:05
User entered 'No (N)'	System	05 Aug 2020 01:15:05

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-04T21:15:00', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '1a690d61-2750-4fb3-8611-2c87f554858c'	System	05 Aug 2020 01:15:05
User entered '04 Aug 2020 21:15'	System	05 Aug 2020 01:15:05

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 12:00'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 11:59'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	31 Jul 2020 20:27:08
User entered 'Day 6'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 08:42:00**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-05T18:57:43', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '1d84d157-323a-4568-9bf3-aa8f84a25cbd'	System	05 Aug 2020 22:57:55
User entered 'Yes (Y)'	System	05 Aug 2020 22:57:55

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 08:42:00**

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-05T18:57:49', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '1d84d157-323a-4568-9bf3-aa8f84a25cbd'	System	05 Aug 2020 22:57:55
User entered '97.9'	System	05 Aug 2020 22:57:55

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 08:42:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-05T18:57:51', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '1d84d157-323a-4568-9bf3-aa8f84a25cbd'	System	05 Aug 2020 22:57:55
User entered 'No (N)'	System	05 Aug 2020 22:57:55



**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-05T18:57:54', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '1d84d157-323a-4568-9bf3-aa8f84a25cbd'	System	05 Aug 2020 22:57:55
User entered '05 Aug 2020 18:57'	System	05 Aug 2020 22:57:55

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 12:00'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 11:59'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	31 Jul 2020 20:27:08
User entered 'Day 7'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 08:42:00**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-06T18:58:49', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'b2058aa4-27dd-4601-a937-8fa47bef6f12'	System	06 Aug 2020 23:00:06
User entered 'Yes (Y)'	System	06 Aug 2020 23:00:06

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 08:42:00**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-06T18:59:46', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'b2058aa4-27dd-4601-a937-8fa47bef6f12'	System	06 Aug 2020 23:00:06
User entered '96.9'	System	06 Aug 2020 23:00:06

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 08:42:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-06T18:59:49', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'b2058aa4-27dd-4601-a937-8fa47bef6f12'	System	06 Aug 2020 23:00:06
User entered 'No (N)'	System	06 Aug 2020 23:00:06

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-06T19:00:04', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'b2058aa4-27dd-4601-a937-8fa47bef6f12'	System	06 Aug 2020 23:00:06
User entered '06 Aug 2020 19:00'	System	06 Aug 2020 23:00:06



**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 12:00'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 11:59'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	31 Jul 2020 20:27:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 08:42:00**

[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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T16:54:05', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '03e56a68-2bc0-4f72-b957-03512db54c3d'	System	31 Jul 2020 20:54:53
User entered 'None (1)'	System	31 Jul 2020 20:54:53

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T16:54:35', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '03e56a68-2bc0-4f72-b957-03512db54c3d'	System	31 Jul 2020 20:54:53
User entered 'No (N)'	System	31 Jul 2020 20:54:53

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 08:42:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T16:54:38', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '03e56a68-2bc0-4f72-b957-03512db54c3d'	System	31 Jul 2020 20:54:53
User entered 'No (N)'	System	31 Jul 2020 20:54:53

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 08:42:00**

[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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T16:54:44', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '03e56a68-2bc0-4f72-b957-03512db54c3d'	System	31 Jul 2020 20:54:53
User entered 'None (1)'	System	31 Jul 2020 20:54:53

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T16:54:51', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '03e56a68-2bc0-4f72-b957-03512db54c3d'	System	31 Jul 2020 20:54:53
User entered '31 Jul 2020 16:54'	System	31 Jul 2020 20:54:53



**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Jul 2020 16:40'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Jul 2020 19:10'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	31 Jul 2020 20:27:08
User entered 'Day 1, after vaccination (at home)'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 08:42:00**

[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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T20:13:42', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'bc75405e-b34b-4941-9bf8-6a43f0ec8eeb'	System	01 Aug 2020 00:13:57
User entered 'None (1)'	System	01 Aug 2020 00:13:57

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T20:13:45', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'bc75405e-b34b-4941-9bf8-6a43f0ec8eeb'	System	01 Aug 2020 00:13:57
User entered 'No (N)'	System	01 Aug 2020 00:13:57

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T20:13:49', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'bc75405e-b34b-4941-9bf8-6a43f0ec8eeb'	System	01 Aug 2020 00:13:57
User entered 'No (N)'	System	01 Aug 2020 00:13:57

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 08:42:00**

[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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T20:13:53', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'bc75405e-b34b-4941-9bf8-6a43f0ec8eeb'	System	01 Aug 2020 00:13:57
User entered 'None (1)'	System	01 Aug 2020 00:13:57

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T20:13:56', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'bc75405e-b34b-4941-9bf8-6a43f0ec8eeb'	System	01 Aug 2020 00:13:57
User entered '31 Jul 2020 20:13'	System	01 Aug 2020 00:13:57



**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Jul 2020 20:05'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 11:59'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	31 Jul 2020 20:27:08
User entered 'Day 2'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 08:42:00**

[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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-01T18:28:49', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '5a95a813-4a3f-41e1-ad45-e9ba179064e9'	System	01 Aug 2020 22:30:04
User entered 'Does not interfere with activity (2)'	System	01 Aug 2020 22:30:04

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-01T18:28:54', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '5a95a813-4a3f-41e1-ad45-e9ba179064e9'	System	01 Aug 2020 22:30:04
User entered 'No (N)'	System	01 Aug 2020 22:30:04

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-01T18:29:45', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '5a95a813-4a3f-41e1-ad45-e9ba179064e9'	System	01 Aug 2020 22:30:04
User entered 'No (N)'	System	01 Aug 2020 22:30:04

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 08:42:00**

[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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-01T18:29:55', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '5a95a813-4a3f-41e1-ad45-e9ba179064e9' User entered 'None (1)'	System	01 Aug 2020 22:30:04
	System	01 Aug 2020 22:30:04

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-01T18:30:03', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '5a95a813-4a3f-41e1-ad45-e9ba179064e9'	System	01 Aug 2020 22:30:04
User entered '01 Aug 2020 18:30'	System	01 Aug 2020 22:30:04



**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 12:00'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 11:59'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	31 Jul 2020 20:27:08
User entered 'Day 3'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 08:42:00**

[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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-02T19:15:15', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '21153255-9ace-4b4f-b7e2-58822ea483df' User entered 'None (1)'	System	02 Aug 2020 23:15:29

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-02T19:15:18', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '21153255-9ace-4b4f-b7e2-58822ea483df'	System	02 Aug 2020 23:15:29
User entered 'No (N)'	System	02 Aug 2020 23:15:29

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-02T19:15:21', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '21153255-9ace-4b4f-b7e2-58822ea483df'	System	02 Aug 2020 23:15:29
User entered 'No (N)'	System	02 Aug 2020 23:15:29

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 08:42:00**

[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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-02T19:15:24', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '21153255-9ace-4b4f-b7e2-58822ea483df' User entered 'None (1)'	System	02 Aug 2020 23:15:29
	System	02 Aug 2020 23:15:29

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-02T19:15:27', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '21153255-9ace-4b4f-b7e2-58822ea483df'	System	02 Aug 2020 23:15:29
User entered '02 Aug 2020 19:15'	System	02 Aug 2020 23:15:29



**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 12:00'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 11:59'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	31 Jul 2020 20:27:08
User entered 'Day 4'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 08:42:00**

[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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-03T21:40:00', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'c1eda4c6-9b82-466d-a8ef-5d41a6bfe13a'	System	04 Aug 2020 01:40:15
User entered 'None (1)'	System	04 Aug 2020 01:40:15

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-03T21:40:04', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'c1eda4c6-9b82-466d-a8ef-5d41a6bfe13a'	System	04 Aug 2020 01:40:15
User entered 'No (N)'	System	04 Aug 2020 01:40:15

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-03T21:40:07', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'c1eda4c6-9b82-466d-a8ef-5d41a6bfe13a'	System	04 Aug 2020 01:40:15
User entered 'No (N)'	System	04 Aug 2020 01:40:15

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 08:42:00**

[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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-03T21:40:10', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'c1eda4c6-9b82-466d-a8ef-5d41a6bfe13a'	System	04 Aug 2020 01:40:15
User entered 'None (1)'	System	04 Aug 2020 01:40:15

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-03T21:40:13', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'c1eda4c6-9b82-466d-a8ef-5d41a6bfe13a'	System	04 Aug 2020 01:40:15
User entered '03 Aug 2020 21:40'	System	04 Aug 2020 01:40:15



**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 12:00'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 11:59'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	31 Jul 2020 20:27:08
User entered 'Day 5'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 08:42:00**

[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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-04T21:15:04', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'bc217a52-ad4a-4cc9-90f3-3f58caa2c051'	System	05 Aug 2020 01:15:16
User entered 'None (1)'	System	05 Aug 2020 01:15:16

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-04T21:15:06', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'bc217a52-ad4a-4cc9-90f3-3f58caa2c051'	System	05 Aug 2020 01:15:16
User entered 'No (N)'	System	05 Aug 2020 01:15:16

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-04T21:15:08', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'bc217a52-ad4a-4cc9-90f3-3f58caa2c051'	System	05 Aug 2020 01:15:16
User entered 'No (N)'	System	05 Aug 2020 01:15:16

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 08:42:00**

[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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-04T21:15:11', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'bc217a52-ad4a-4cc9-90f3-3f58caa2c051'	System	05 Aug 2020 01:15:16
User entered 'None (1)'	System	05 Aug 2020 01:15:16

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-04T21:15:14', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'bc217a52-ad4a-4cc9-90f3-3f58caa2c051'	System	05 Aug 2020 01:15:16
User entered '04 Aug 2020 21:15'	System	05 Aug 2020 01:15:16



**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 12:00'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 11:59'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	31 Jul 2020 20:27:08
User entered 'Day 6'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 08:42:00**

[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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-05T18:57:58', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'b6fb2f63-09e5-4566-91a9-9158c3439307'	System	05 Aug 2020 22:58:17
User entered 'None (1)'	System	05 Aug 2020 22:58:17

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-05T18:58:00', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'b6fb2f63-09e5-4566-91a9-9158c3439307'	System	05 Aug 2020 22:58:17
User entered 'No (N)'	System	05 Aug 2020 22:58:17

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-05T18:58:02', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'b6fb2f63-09e5-4566-91a9-9158c3439307'	System	05 Aug 2020 22:58:17
User entered 'No (N)'	System	05 Aug 2020 22:58:17

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 08:42:00**

[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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-05T18:58:08', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'b6fb2f63-09e5-4566-91a9-9158c3439307'	System	05 Aug 2020 22:58:17
User entered 'None (1)'	System	05 Aug 2020 22:58:17

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-05T18:58:12', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'b6fb2f63-09e5-4566-91a9-9158c3439307'	System	05 Aug 2020 22:58:17
User entered '05 Aug 2020 18:58'	System	05 Aug 2020 22:58:17



**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 12:00'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 11:59'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	31 Jul 2020 20:27:08
User entered 'Day 7'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 08:42:00**

[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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-06T19:00:09', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '14b29f1f-357f-4bcf-8d3f-6f7341d18c58'	System	06 Aug 2020 23:00:22
User entered 'None (1)'	System	06 Aug 2020 23:00:22

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-06T19:00:12', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '14b29f1f-357f-4bcf-8d3f-6f7341d18c58'	System	06 Aug 2020 23:00:22
User entered 'No (N)'	System	06 Aug 2020 23:00:22

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-06T19:00:14', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '14b29f1f-357f-4bcf-8d3f-6f7341d18c58'	System	06 Aug 2020 23:00:22
User entered 'No (N)'	System	06 Aug 2020 23:00:22

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 08:42:00**

[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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-06T19:00:19', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '14b29f1f-357f-4bcf-8d3f-6f7341d18c58'	System	06 Aug 2020 23:00:22
User entered 'None (1)'	System	06 Aug 2020 23:00:22

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-06T19:00:21', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '14b29f1f-357f-4bcf-8d3f-6f7341d18c58'	System	06 Aug 2020 23:00:22
User entered '06 Aug 2020 19:00'	System	06 Aug 2020 23:00:22



**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 12:00'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 11:59'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	31 Jul 2020 20:27:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 08:42:00**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T16:54:56', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a4d3cc26-f5bf-4c08-a9ef-be1afb7b7d47'	System	31 Jul 2020 20:55:18
User entered 'None (0)'	System	31 Jul 2020 20:55:18

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 08:42:00**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T16:54:59', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a4d3cc26-f5bf-4c08-a9ef-be1afb7b7d47'	System	31 Jul 2020 20:55:18
User entered 'None (0)'	System	31 Jul 2020 20:55:18

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 08:42:00**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T16:55:03', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a4d3cc26-f5bf-4c08-a9ef-be1afb7b7d47'	System	31 Jul 2020 20:55:18
User entered 'None (0)'	System	31 Jul 2020 20:55:18

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 08:42:00**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T16:55:05', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a4d3cc26-f5bf-4c08-a9ef-be1afb7b7d47'	System	31 Jul 2020 20:55:18
User entered 'None (0)'	System	31 Jul 2020 20:55:18

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 08:42:00**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T16:55:07', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a4d3cc26-f5bf-4c08-a9ef-be1afb7b7d47'	System	31 Jul 2020 20:55:18
User entered 'None (0)'	System	31 Jul 2020 20:55:18



**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 08:42:00**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T16:55:09', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a4d3cc26-f5bf-4c08-a9ef-be1afb7b7d47'	System	31 Jul 2020 20:55:18
User entered 'None (0)'	System	31 Jul 2020 20:55:18

US3022103

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 08:42:00

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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T16:55:13', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a4d3cc26-f5bf-4c08-a9ef-be1afb7b7d47'	System	31 Jul 2020 20:55:18
User entered 'No (N)'	System	31 Jul 2020 20:55:18

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T16:55:16', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a4d3cc26-f5bf-4c08-a9ef-be1afb7b7d47'	System	31 Jul 2020 20:55:18
User entered '31 Jul 2020 16:55'	System	31 Jul 2020 20:55:18

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Jul 2020 16:40'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Jul 2020 19:10'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	31 Jul 2020 20:27:08
User entered 'Day 1, after vaccination (at home)'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 08:42:00**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T20:14:00', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a63c356b-4c6f-4a35-b963-d4dd5ca6d0ca'	System	01 Aug 2020 00:14:28
User entered 'None (0)'	System	01 Aug 2020 00:14:28

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 08:42:00**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T20:14:04', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a63c356b-4c6f-4a35-b963-d4dd5ca6d0ca'	System	01 Aug 2020 00:14:28
User entered 'None (0)'	System	01 Aug 2020 00:14:28



**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 08:42:00**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T20:14:06', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a63c356b-4c6f-4a35-b963-d4dd5ca6d0ca'	System	01 Aug 2020 00:14:28
User entered 'None (0)'	System	01 Aug 2020 00:14:28

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 08:42:00**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T20:14:10', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a63c356b-4c6f-4a35-b963-d4dd5ca6d0ca' User entered 'None (0)'	System	01 Aug 2020 00:14:28
	System	01 Aug 2020 00:14:28

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 08:42:00**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T20:14:12', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a63c356b-4c6f-4a35-b963-d4dd5ca6d0ca'	System	01 Aug 2020 00:14:28
User entered 'None (0)'	System	01 Aug 2020 00:14:28

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 08:42:00**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T20:14:14', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a63c356b-4c6f-4a35-b963-d4dd5ca6d0ca'	System	01 Aug 2020 00:14:28
User entered 'None (0)'	System	01 Aug 2020 00:14:28

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 08:42:00**

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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T20:14:19', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a63c356b-4c6f-4a35-b963-d4dd5ca6d0ca'	System	01 Aug 2020 00:14:28
User entered 'No (N)'	System	01 Aug 2020 00:14:28

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T20:14:24', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a63c356b-4c6f-4a35-b963-d4dd5ca6d0ca' User entered '31 Jul 2020 20:14'	System	01 Aug 2020 00:14:28
	System	01 Aug 2020 00:14:28

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Jul 2020 20:05'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 11:59'	System	31 Jul 2020 20:27:08



**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	31 Jul 2020 20:27:08
User entered 'Day 2'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 08:42:00**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-01T18:30:29', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '27920f58-c877-4419-85e3-f36ab7c66ec1'	System	01 Aug 2020 22:31:35
User entered 'No interference with activity (1)'	System	01 Aug 2020 22:31:35

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 08:42:00**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-01T18:30:38', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '27920f58-c877-4419-85e3-f36ab7c66ec1'	System	01 Aug 2020 22:31:35
User entered 'Some interference with activity (2)'	System	01 Aug 2020 22:31:35

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 08:42:00**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-01T18:30:48', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '27920f58-c877-4419-85e3-f36ab7c66ec1'	System	01 Aug 2020 22:31:35
User entered 'None (0)'	System	01 Aug 2020 22:31:35

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 08:42:00**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-01T18:30:58', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '27920f58-c877-4419-85e3-f36ab7c66ec1'	System	01 Aug 2020 22:31:35
User entered 'None (0)'	System	01 Aug 2020 22:31:35

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 08:42:00**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-01T18:31:04', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '27920f58-c877-4419-85e3-f36ab7c66ec1'	System	01 Aug 2020 22:31:35
User entered 'None (0)'	System	01 Aug 2020 22:31:35

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 08:42:00**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-01T18:31:09', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '27920f58-c877-4419-85e3-f36ab7c66ec1'	System	01 Aug 2020 22:31:35
User entered 'No interference with activity (1)'	System	01 Aug 2020 22:31:35

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 08:42:00**

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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-01T18:31:13', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '27920f58-c877-4419-85e3-f36ab7c66ec1'	System	01 Aug 2020 22:31:35
User entered 'No (N)'	System	01 Aug 2020 22:31:35



**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-01T18:31:29', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '27920f58-c877-4419-85e3-f36ab7c66ec1'	System	01 Aug 2020 22:31:35
User entered '01 Aug 2020 18:31'	System	01 Aug 2020 22:31:35

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 12:00'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 11:59'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	31 Jul 2020 20:27:08
User entered 'Day 3'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 08:42:00**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-02T19:15:32', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '79b4b9be-3ff7-49a4-ac0a-c07c0dc59ac5'	System	02 Aug 2020 23:15:59
User entered 'None (0)'	System	02 Aug 2020 23:15:59

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 08:42:00**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-02T19:15:40', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '79b4b9be-3ff7-49a4-ac0a-c07c0dc59ac5'	System	02 Aug 2020 23:15:59
User entered 'None (0)'	System	02 Aug 2020 23:15:59

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 08:42:00**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-02T19:15:43', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '79b4b9be-3ff7-49a4-ac0a-c07c0dc59ac5'	System	02 Aug 2020 23:15:59
User entered 'None (0)'	System	02 Aug 2020 23:15:59

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 08:42:00**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-02T19:15:45', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '79b4b9be-3ff7-49a4-ac0a-c07c0dc59ac5'	System	02 Aug 2020 23:15:59
User entered 'None (0)'	System	02 Aug 2020 23:15:59



**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 08:42:00**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-02T19:15:47', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '79b4b9be-3ff7-49a4-ac0a-c07c0dc59ac5'	System	02 Aug 2020 23:15:59
User entered 'None (0)'	System	02 Aug 2020 23:15:59

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 08:42:00**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-02T19:15:50', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '79b4b9be-3ff7-49a4-ac0a-c07c0dc59ac5'	System	02 Aug 2020 23:15:59
User entered 'None (0)'	System	02 Aug 2020 23:15:59

US3022103

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 08:42:00

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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-02T19:15:53', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '79b4b9be-3ff7-49a4-ac0a-c07c0dc59ac5'	System	02 Aug 2020 23:15:59
User entered 'No (N)'	System	02 Aug 2020 23:15:59

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-02T19:15:57', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '79b4b9be-3ff7-49a4-ac0a-c07c0dc59ac5'	System	02 Aug 2020 23:15:59
User entered '02 Aug 2020 19:15'	System	02 Aug 2020 23:15:59

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 12:00'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 11:59'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	31 Jul 2020 20:27:08
User entered 'Day 4'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 08:42:00**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-03T21:40:16', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '514560f4-fd2f-4e5d-b4fe-fc3d87cbfd41'	System	04 Aug 2020 01:40:47
User entered 'None (0)'	System	04 Aug 2020 01:40:47



**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 08:42:00**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-03T21:40:22', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '514560f4-fd2f-4e5d-b4fe-fc3d87cbfd41'	System	04 Aug 2020 01:40:47
User entered 'No interference with activity (1)'	System	04 Aug 2020 01:40:47

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 08:42:00**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-03T21:40:27', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '514560f4-fd2f-4e5d-b4fe-fc3d87cbfd41'	System	04 Aug 2020 01:40:47
User entered 'None (0)'	System	04 Aug 2020 01:40:47

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 08:42:00**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-03T21:40:32', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '514560f4-fd2f-4e5d-b4fe-fc3d87cbfd41'	System	04 Aug 2020 01:40:47
User entered 'No interference with activity (1)'	System	04 Aug 2020 01:40:47

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 08:42:00**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-03T21:40:35', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '514560f4-fd2f-4e5d-b4fe-fc3d87cbfd41'	System	04 Aug 2020 01:40:47
User entered 'None (0)'	System	04 Aug 2020 01:40:47

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 08:42:00**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-03T21:40:36', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '514560f4-fd2f-4e5d-b4fe-fc3d87cbfd41'	System	04 Aug 2020 01:40:47
User entered 'None (0)'	System	04 Aug 2020 01:40:47

US3022103

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 08:42:00

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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-03T21:40:40', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '514560f4-fd2f-4e5d-b4fe-fc3d87cbfd41'	System	04 Aug 2020 01:40:47
User entered 'No (N)'	System	04 Aug 2020 01:40:47

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-03T21:40:46', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '514560f4-fd2f-4e5d-b4fe-fc3d87cbfd41'	System	04 Aug 2020 01:40:47
User entered '03 Aug 2020 21:40'	System	04 Aug 2020 01:40:47

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 12:00'	System	31 Jul 2020 20:27:08



**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 11:59'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	31 Jul 2020 20:27:08
User entered 'Day 5'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 08:42:00**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-04T21:15:17', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '2188b074-2bce-42b0-8963-9e8f245269e5'	System	05 Aug 2020 01:15:39
User entered 'None (0)'	System	05 Aug 2020 01:15:39

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 08:42:00**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-04T21:15:20', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '2188b074-2bce-42b0-8963-9e8f245269e5'	System	05 Aug 2020 01:15:39
User entered 'None (0)'	System	05 Aug 2020 01:15:39

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 08:42:00**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-04T21:15:22', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '2188b074-2bce-42b0-8963-9e8f245269e5'	System	05 Aug 2020 01:15:39
User entered 'None (0)'	System	05 Aug 2020 01:15:39

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 08:42:00**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-04T21:15:25', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '2188b074-2bce-42b0-8963-9e8f245269e5'	System	05 Aug 2020 01:15:39
User entered 'None (0)'	System	05 Aug 2020 01:15:39

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 08:42:00**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-04T21:15:27', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '2188b074-2bce-42b0-8963-9e8f245269e5'	System	05 Aug 2020 01:15:39
User entered 'None (0)'	System	05 Aug 2020 01:15:39

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 08:42:00**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-04T21:15:29', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '2188b074-2bce-42b0-8963-9e8f245269e5'	System	05 Aug 2020 01:15:39
User entered 'None (0)'	System	05 Aug 2020 01:15:39



**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 08:42:00**

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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-04T21:15:32', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '2188b074-2bce-42b0-8963-9e8f245269e5'	System	05 Aug 2020 01:15:39
User entered 'No (N)'	System	05 Aug 2020 01:15:39

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-04T21:15:36', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '2188b074-2bce-42b0-8963-9e8f245269e5'	System	05 Aug 2020 01:15:39
User entered '04 Aug 2020 21:15'	System	05 Aug 2020 01:15:39

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 12:00'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 11:59'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	31 Jul 2020 20:27:08
User entered 'Day 6'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 08:42:00**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-05T18:58:16', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '58e93a88-81fa-4b8b-ae89-427f12ac67a2'	System	05 Aug 2020 22:58:43
User entered 'None (0)'	System	05 Aug 2020 22:58:43

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 08:42:00**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-05T18:58:26', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '58e93a88-81fa-4b8b-ae89-427f12ac67a2'	System	05 Aug 2020 22:58:43
User entered 'None (0)'	System	05 Aug 2020 22:58:43

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 08:42:00**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-05T18:58:28', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '58e93a88-81fa-4b8b-ae89-427f12ac67a2'	System	05 Aug 2020 22:58:43
User entered 'None (0)'	System	05 Aug 2020 22:58:43



**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 08:42:00**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-05T18:58:29', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '58e93a88-81fa-4b8b-ae89-427f12ac67a2'	System	05 Aug 2020 22:58:43
User entered 'None (0)'	System	05 Aug 2020 22:58:43

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 08:42:00**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-05T18:58:31', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '58e93a88-81fa-4b8b-ae89-427f12ac67a2'	System	05 Aug 2020 22:58:43
User entered 'None (0)'	System	05 Aug 2020 22:58:43

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 08:42:00**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-05T18:58:33', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '58e93a88-81fa-4b8b-ae89-427f12ac67a2'	System	05 Aug 2020 22:58:43
User entered 'None (0)'	System	05 Aug 2020 22:58:43

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 08:42:00**

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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-05T18:58:36', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '58e93a88-81fa-4b8b-ae89-427f12ac67a2'	System	05 Aug 2020 22:58:43
User entered 'No (N)'	System	05 Aug 2020 22:58:43

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-05T18:58:39', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '58e93a88-81fa-4b8b-ae89-427f12ac67a2'	System	05 Aug 2020 22:58:43
User entered '05 Aug 2020 18:58'	System	05 Aug 2020 22:58:43

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 12:00'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 11:59'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	31 Jul 2020 20:27:08
User entered 'Day 7'	System	31 Jul 2020 20:27:08



**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 08:42:00**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-06T19:00:24', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'c36d4b01-9fbe-4041-9721-a98b52f12b9f'	System	06 Aug 2020 23:01:18
User entered 'None (0)'	System	06 Aug 2020 23:01:18

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 08:42:00**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-06T19:00:39', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'c36d4b01-9fbe-4041-9721-a98b52f12b9f'	System	06 Aug 2020 23:01:18
User entered 'None (0)'	System	06 Aug 2020 23:01:18

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 08:42:00**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-06T19:01:00', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'c36d4b01-9fbe-4041-9721-a98b52f12b9f'	System	06 Aug 2020 23:01:18
User entered 'None (0)'	System	06 Aug 2020 23:01:18

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 08:42:00**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-06T19:01:02', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'c36d4b01-9fbe-4041-9721-a98b52f12b9f'	System	06 Aug 2020 23:01:18
User entered 'None (0)'	System	06 Aug 2020 23:01:18

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 08:42:00**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-06T19:01:04', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'c36d4b01-9fbe-4041-9721-a98b52f12b9f'	System	06 Aug 2020 23:01:18
User entered 'None (0)'	System	06 Aug 2020 23:01:18

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 08:42:00**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-06T19:01:06', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'c36d4b01-9fbe-4041-9721-a98b52f12b9f'	System	06 Aug 2020 23:01:18
User entered 'None (0)'	System	06 Aug 2020 23:01:18

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 08:42:00**

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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-06T19:01:08', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'c36d4b01-9fbe-4041-9721-a98b52f12b9f'	System	06 Aug 2020 23:01:18
User entered 'No (N)'	System	06 Aug 2020 23:01:18

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-06T19:01:15', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'c36d4b01-9fbe-4041-9721-a98b52f12b9f' User entered '06 Aug 2020 19:01'	System	06 Aug 2020 23:01:18
	System	06 Aug 2020 23:01:18



**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 12:00'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 11:59'	System	31 Jul 2020 20:27:08

**US3022103**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 08:42:00**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	10 Aug 2020 20:33:31

**US3022103**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
User entered '10 Aug 2020'	Shanice Bennett (b) (4) (b) (4)	10 Aug 2020 20:33:31

**US3022103**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 08:42:00**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Shanice Bennett (b) (4) (b) (4)	10 Aug 2020 20:33:31

**US3022103**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 08:42:00**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Aug 2020 20:33:31

**US3022103**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	10 Aug 2020 20:33:35

**US3022103**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 08:42:00**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Aug 2020 20:33:35



**US3022103**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 08:42:00**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	17 Aug 2020 22:52:25

**US3022103**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
User entered '17 Aug 2020'	Shanice Bennett (b) (4) (b) (4)	17 Aug 2020 22:52:25

**US3022103**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 08:42:00**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Shanice Bennett (b) (4) (b) (4)	17 Aug 2020 22:52:25

**US3022103**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 08:42:00**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	17 Aug 2020 22:52:25

**US3022103**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	17 Aug 2020 22:52:29

**US3022103**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 08:42:00**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Aug 2020 22:52:29

**US3022103**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 08:42:00**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Morgan Deal (b) (4) (b) (4)	12 Nov 2020 22:20:26

**US3022103**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 08:42:00**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020'	Morgan Deal (b) (4) (b) (4)	12 Nov 2020 22:20:26



**US3022103**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 08:42:00**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Morgan Deal (b) (4) (b) (4)	12 Nov 2020 22:20:26

**US3022103**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 08:42:00**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	Morgan Deal (b) (4) (b) (4)	12 Nov 2020 22:20:26

**US3022103**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Morgan Deal (b) (4) (b) (4)	12 Nov 2020 22:20:31

**US3022103**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 08:42:00**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Nov 2020 22:20:31

**US3022103**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 08:42:00**

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Chevon Roberts (b) (4) (b) (4)	23 Nov 2020 17:12:03

**US3022103**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 08:42:00**

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	Chevon Roberts (b) (4) (b) (4)	23 Nov 2020 17:12:03

**US3022103**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
User entered empty.	Chevon Roberts (b) (4) (b) (4)	23 Nov 2020 17:12:03

**US3022103**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 08:42:00**

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	23 Nov 2020 17:12:03



US3022103

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:42:00

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '23 Nov 2020'	Chevon Roberts (b) (4) (b) (4)	23 Nov 2020 17:12:03

**US3022103**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
User entered '12:04'	Chevon Roberts (b) (4) (b) (4)	23 Nov 2020 17:12:03

**US3022103**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
User entered '23 Nov 2020 12:04'	System	23 Nov 2020 17:12:03

US3022103

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:42:00

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Chevon Roberts (b) (4) (b) (4)	23 Nov 2020 17:12:03

**US3022103**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 08:42:00**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	23 Nov 2020 17:12:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 08:42:00**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T12:33:25', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '9e2dc3b2-3603-4cd5-a128-534a7a133512'	System	23 Nov 2020 17:33:43
User entered 'Yes (Y)'	System	23 Nov 2020 17:33:43



**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 08:42:00**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T12:33:32', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '9e2dc3b2-3603-4cd5-a128-534a7a133512'	System	23 Nov 2020 17:33:43
User entered '98.4'	System	23 Nov 2020 17:33:43

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 08:42:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T12:33:35', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '9e2dc3b2-3603-4cd5-a128-534a7a133512'	System	23 Nov 2020 17:33:43
User entered 'No (N)'	System	23 Nov 2020 17:33:43

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T12:33:40', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '9e2dc3b2-3603-4cd5-a128-534a7a133512'	System	23 Nov 2020 17:33:43
User entered '23 Nov 2020 12:33'	System	23 Nov 2020 17:33:43

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Nov 2020 12:24'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Nov 2020 14:54'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	23 Nov 2020 17:12:03
User entered 'Day 1, after vaccination (at home)'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 08:42:00**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T17:46:29', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'b7efec8e-28d4-4728-8b85-3224c52f04c5'	System	23 Nov 2020 22:46:44
User entered 'Yes (Y)'	System	23 Nov 2020 22:46:44

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 08:42:00**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T17:46:35', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'b7efec8e-28d4-4728-8b85-3224c52f04c5'	System	23 Nov 2020 22:46:44
User entered '98.1'	System	23 Nov 2020 22:46:44



US3022103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 08:42:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T17:46:37', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'b7efec8e-28d4-4728-8b85-3224c52f04c5'	System	23 Nov 2020 22:46:44
User entered 'No (N)'	System	23 Nov 2020 22:46:44

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T17:46:41', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'b7efec8e-28d4-4728-8b85-3224c52f04c5'	System	23 Nov 2020 22:46:44
User entered '23 Nov 2020 17:46'	System	23 Nov 2020 22:46:44

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Nov 2020 15:49'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Nov 2020 11:59'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	23 Nov 2020 17:12:03
User entered 'Day 2'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 08:42:00**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-24T12:27:08', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '2f913386-2b42-4b0b-8f3c-a4722ae8a08c'	System	24 Nov 2020 17:30:57
User entered 'Yes (Y)'	System	24 Nov 2020 17:30:57

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 08:42:00**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-24T12:30:14', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '2f913386-2b42-4b0b-8f3c-a4722ae8a08c'	System	24 Nov 2020 17:30:57
User entered '99.2'	System	24 Nov 2020 17:30:57

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 08:42:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-24T12:30:33', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '2f913386-2b42-4b0b-8f3c-a4722ae8a08c'	System	24 Nov 2020 17:30:57
User entered 'Yes (Y)'	System	24 Nov 2020 17:30:57



US3022103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 08:42:00

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

Audit	User	Time (GMT)
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-24T12:30:46', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '2f913386-2b42-4b0b-8f3c-a4722ae8a08c'	System	24 Nov 2020 17:30:57
User entered '1'	System	24 Nov 2020 17:30:57

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 08:42:00**

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-24T12:30:46', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '2f913386-2b42-4b0b-8f3c-a4722ae8a08c'	System	24 Nov 2020 17:30:57
User entered '0'	System	24 Nov 2020 17:30:57

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-24T12:30:52', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '2f913386-2b42-4b0b-8f3c-a4722ae8a08c'	System	24 Nov 2020 17:30:57
User entered '24 Nov 2020 12:30'	System	24 Nov 2020 17:30:57

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Nov 2020 12:00'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Nov 2020 11:59'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	23 Nov 2020 17:12:03
User entered 'Day 3'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Nov 2020 12:00'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Nov 2020 11:59'	System	23 Nov 2020 17:12:03



**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	23 Nov 2020 17:12:03
User entered 'Day 4'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Nov 2020 12:00'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Nov 2020 11:59'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	23 Nov 2020 17:12:03
User entered 'Day 5'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Nov 2020 12:00'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Nov 2020 11:59'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	23 Nov 2020 17:12:03
User entered 'Day 6'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Nov 2020 12:00'	System	23 Nov 2020 17:12:03



**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Nov 2020 11:59'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	23 Nov 2020 17:12:03
User entered 'Day 7'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Nov 2020 12:00'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Nov 2020 11:59'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	23 Nov 2020 17:12:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 08:42:00**

[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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T12:33:49', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '1111100d-6547-493b-9cb9-b4b595a35dd8'	System	23 Nov 2020 17:34:22
User entered 'None (1)'	System	23 Nov 2020 17:34:22

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T12:34:08', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '1111100d-6547-493b-9cb9-b4b595a35dd8'	System	23 Nov 2020 17:34:22
User entered 'No (N)'	System	23 Nov 2020 17:34:22

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T12:34:10', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '1111100d-6547-493b-9cb9-b4b595a35dd8'	System	23 Nov 2020 17:34:22
User entered 'No (N)'	System	23 Nov 2020 17:34:22



**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 08:42:00**

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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T12:34:16', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '1111100d-6547-493b-9cb9-b4b595a35dd8'	System	23 Nov 2020 17:34:22
User entered 'None (1)'	System	23 Nov 2020 17:34:22

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T12:34:19', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '1111100d-6547-493b-9cb9-b4b595a35dd8'	System	23 Nov 2020 17:34:22
User entered '23 Nov 2020 12:34'	System	23 Nov 2020 17:34:22

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Nov 2020 12:24'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Nov 2020 14:54'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	23 Nov 2020 17:12:03
User entered 'Day 1, after vaccination (at home)'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 08:42:00**

[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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T17:46:48', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a4341e28-bd17-4b48-8217-fc0ccf1ae0b4'	System	23 Nov 2020 22:47:20
User entered 'Does not interfere with activity (2)'	System	23 Nov 2020 22:47:20

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T17:46:51', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a4341e28-bd17-4b48-8217-fc0ccf1ae0b4'	System	23 Nov 2020 22:47:20
User entered 'No (N)'	System	23 Nov 2020 22:47:20

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T17:47:09', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a4341e28-bd17-4b48-8217-fc0ccf1ae0b4'	System	23 Nov 2020 22:47:20
User entered 'No (N)'	System	23 Nov 2020 22:47:20



US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 08:42:00

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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T17:47:13', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a4341e28-bd17-4b48-8217-fc0ccf1ae0b4'	System	23 Nov 2020 22:47:20
User entered 'None (1)'	System	23 Nov 2020 22:47:20

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T17:47:16', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a4341e28-bd17-4b48-8217-fc0ccf1ae0b4'	System	23 Nov 2020 22:47:20
User entered '23 Nov 2020 17:47'	System	23 Nov 2020 22:47:20

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Nov 2020 15:49'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Nov 2020 11:59'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	23 Nov 2020 17:12:03
User entered 'Day 2'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 08:42:00**

[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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-24T12:31:00', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '29d4a129-98a4-488e-95d6-511067e25d2c'	System	24 Nov 2020 17:31:19
User entered 'Does not interfere with activity (2)'	System	24 Nov 2020 17:31:19

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-24T12:31:03', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '29d4a129-98a4-488e-95d6-511067e25d2c'	System	24 Nov 2020 17:31:19
User entered 'No (N)'	System	24 Nov 2020 17:31:19

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-24T12:31:09', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '29d4a129-98a4-488e-95d6-511067e25d2c'	System	24 Nov 2020 17:31:19
User entered 'No (N)'	System	24 Nov 2020 17:31:19



**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 08:42:00**

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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-24T12:31:13', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '29d4a129-98a4-488e-95d6-511067e25d2c'	System	24 Nov 2020 17:31:19
User entered 'Does not interfere with activity (2)'	System	24 Nov 2020 17:31:19

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-24T12:31:16', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '29d4a129-98a4-488e-95d6-511067e25d2c'	System	24 Nov 2020 17:31:19
User entered '24 Nov 2020 12:31'	System	24 Nov 2020 17:31:19

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Nov 2020 12:00'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Nov 2020 11:59'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	23 Nov 2020 17:12:03
User entered 'Day 3'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Nov 2020 12:00'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Nov 2020 11:59'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	23 Nov 2020 17:12:03
User entered 'Day 4'	System	23 Nov 2020 17:12:03



**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Nov 2020 12:00'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Nov 2020 11:59'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	23 Nov 2020 17:12:03
User entered 'Day 5'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Nov 2020 12:00'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Nov 2020 11:59'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	23 Nov 2020 17:12:03
User entered 'Day 6'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Nov 2020 12:00'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Nov 2020 11:59'	System	23 Nov 2020 17:12:03



**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	23 Nov 2020 17:12:03
User entered 'Day 7'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Nov 2020 12:00'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Nov 2020 11:59'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	23 Nov 2020 17:12:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 08:42:00**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T12:34:24', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '70dcd23b-3720-4bfe-828c-603dfbd0308c'	System	23 Nov 2020 17:34:49
User entered 'None (0)'	System	23 Nov 2020 17:34:49

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 08:42:00**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T12:34:26', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '70dcd23b-3720-4bfe-828c-603dfbd0308c'	System	23 Nov 2020 17:34:49
User entered 'None (0)'	System	23 Nov 2020 17:34:49

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 08:42:00**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T12:34:29', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '70dcd23b-3720-4bfe-828c-603dfbd0308c'	System	23 Nov 2020 17:34:49
User entered 'None (0)'	System	23 Nov 2020 17:34:49

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 08:42:00**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T12:34:32', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '70dcd23b-3720-4bfe-828c-603dfbd0308c'	System	23 Nov 2020 17:34:49
User entered 'None (0)'	System	23 Nov 2020 17:34:49



**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 08:42:00**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T12:34:34', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '70dcd23b-3720-4bfe-828c-603dfbd0308c'	System	23 Nov 2020 17:34:49
User entered 'None (0)'	System	23 Nov 2020 17:34:49

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 08:42:00**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T12:34:36', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '70dcd23b-3720-4bfe-828c-603dfbd0308c'	System	23 Nov 2020 17:34:49
User entered 'None (0)'	System	23 Nov 2020 17:34:49

US3022103

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 08:42:00

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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T12:34:41', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '70dcd23b-3720-4bfe-828c-603dfbd0308c'	System	23 Nov 2020 17:34:49
User entered 'No (N)'	System	23 Nov 2020 17:34:49

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T12:34:44', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '70dcd23b-3720-4bfe-828c-603dfbd0308c'	System	23 Nov 2020 17:34:49
User entered '23 Nov 2020 12:34'	System	23 Nov 2020 17:34:49

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Nov 2020 12:24'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Nov 2020 14:54'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	23 Nov 2020 17:12:03
User entered 'Day 1, after vaccination (at home)'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 08:42:00**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T17:47:24', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '4330b896-f59b-4337-8e3b-099409c048d0'	System	23 Nov 2020 22:48:34
User entered 'None (0)'	System	23 Nov 2020 22:48:34



**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 08:42:00**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T17:47:41', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '4330b896-f59b-4337-8e3b-099409c048d0'	System	23 Nov 2020 22:48:34
User entered 'No interference with activity (1)'	System	23 Nov 2020 22:48:34

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 08:42:00**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T17:47:47', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '4330b896-f59b-4337-8e3b-099409c048d0'	System	23 Nov 2020 22:48:34
User entered 'None (0)'	System	23 Nov 2020 22:48:34

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 08:42:00**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T17:47:50', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '4330b896-f59b-4337-8e3b-099409c048d0'	System	23 Nov 2020 22:48:34
User entered 'None (0)'	System	23 Nov 2020 22:48:34

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 08:42:00**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T17:47:52', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '4330b896-f59b-4337-8e3b-099409c048d0'	System	23 Nov 2020 22:48:34
User entered 'None (0)'	System	23 Nov 2020 22:48:34

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 08:42:00**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T17:47:55', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '4330b896-f59b-4337-8e3b-099409c048d0'	System	23 Nov 2020 22:48:34
User entered 'None (0)'	System	23 Nov 2020 22:48:34

US3022103

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 08:42:00

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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T17:48:26', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '4330b896-f59b-4337-8e3b-099409c048d0'	System	23 Nov 2020 22:48:34
User entered 'No (N)'	System	23 Nov 2020 22:48:34

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T17:48:29', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '4330b896-f59b-4337-8e3b-099409c048d0'	System	23 Nov 2020 22:48:34
User entered '23 Nov 2020 17:48'	System	23 Nov 2020 22:48:34

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Nov 2020 15:49'	System	23 Nov 2020 17:12:03



**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Nov 2020 11:59'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	23 Nov 2020 17:12:03
User entered 'Day 2'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 08:42:00**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-24T12:31:29', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a3e32140-b62e-49a4-a544-964ca2cf344a'	System	24 Nov 2020 17:32:20
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	24 Nov 2020 17:32:20

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 08:42:00**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-24T12:31:36', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a3e32140-b62e-49a4-a544-964ca2cf344a'	System	24 Nov 2020 17:32:20
User entered 'Some interference with activity (2)'	System	24 Nov 2020 17:32:20

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 08:42:00**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-24T12:31:43', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a3e32140-b62e-49a4-a544-964ca2cf344a'	System	24 Nov 2020 17:32:20
User entered 'No interference with activity (1)'	System	24 Nov 2020 17:32:20

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 08:42:00**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-24T12:31:53', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a3e32140-b62e-49a4-a544-964ca2cf344a'	System	24 Nov 2020 17:32:20
User entered 'No interference with activity (1)'	System	24 Nov 2020 17:32:20

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 08:42:00**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-24T12:31:59', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a3e32140-b62e-49a4-a544-964ca2cf344a'	System	24 Nov 2020 17:32:20
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	24 Nov 2020 17:32:20

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 08:42:00**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-24T12:32:08', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a3e32140-b62e-49a4-a544-964ca2cf344a'	System	24 Nov 2020 17:32:20
User entered 'No interference with activity (1)'	System	24 Nov 2020 17:32:20



US3022103

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 08:42:00

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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-24T12:32:11', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a3e32140-b62e-49a4-a544-964ca2cf344a'	System	24 Nov 2020 17:32:20
User entered 'No (N)'	System	24 Nov 2020 17:32:20

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-24T12:32:18', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a3e32140-b62e-49a4-a544-964ca2cf344a' User entered '24 Nov 2020 12:32'	System	24 Nov 2020 17:32:20
	System	24 Nov 2020 17:32:20

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Nov 2020 12:00'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Nov 2020 11:59'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	23 Nov 2020 17:12:03
User entered 'Day 3'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Nov 2020 12:00'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Nov 2020 11:59'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	23 Nov 2020 17:12:03
User entered 'Day 4'	System	23 Nov 2020 17:12:03



**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Nov 2020 12:00'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Nov 2020 11:59'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	23 Nov 2020 17:12:03
User entered 'Day 5'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Nov 2020 12:00'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Nov 2020 11:59'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	23 Nov 2020 17:12:03
User entered 'Day 6'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Nov 2020 12:00'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Nov 2020 11:59'	System	23 Nov 2020 17:12:03



**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	23 Nov 2020 17:12:03
User entered 'Day 7'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Nov 2020 12:00'	System	23 Nov 2020 17:12:03

**US3022103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 08:42:00**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Nov 2020 11:59'	System	23 Nov 2020 17:12:03

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	31 Jul 2020 20:27:08
User entered 'Day 64'	System	31 Jul 2020 20:27:08

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-10-01T14:28:06', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '04cbdb18-8fc8-4bc0-933e-59ed2e6ae166'	System	01 Oct 2020 18:28:54
User entered 'Yes (Y)'	System	01 Oct 2020 18:28:54

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

Have you been exposed to someone with 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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-10-01T14:28:13', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '04cbdb18-8fc8-4bc0-933e-59ed2e6ae166'	System	01 Oct 2020 18:28:54
User entered 'No (N)'	System	01 Oct 2020 18:28:54

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-10-01T14:28:20', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '04cbdb18-8fc8-4bc0-933e-59ed2e6ae166'	System	01 Oct 2020 18:28:54
User entered 'No (N)'	System	01 Oct 2020 18:28:54

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-10-01T14:28:25', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '04cbdb18-8fc8-4bc0-933e-59ed2e6ae166'	System	01 Oct 2020 18:28:54
User entered 'Yes (Y)'	System	01 Oct 2020 18:28:54



**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-10-01T14:28:37', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '04cbdb18-8fc8-4bc0-933e-59ed2e6ae166'	System	01 Oct 2020 18:28:54
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	01 Oct 2020 18:28:54

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-10-01T14:28:43', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '04cbdb18-8fc8-4bc0-933e-59ed2e6ae166'	System	01 Oct 2020 18:28:54
User entered '01 Oct 2020 14:28:43'	System	01 Oct 2020 18:28:54

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	31 Jul 2020 20:27:08
User entered '30 Sep 2020 00:01'	System	31 Jul 2020 20:27:08

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	31 Jul 2020 20:27:08
User entered '04 Oct 2020 23:59'	System	31 Jul 2020 20:27:08

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	31 Jul 2020 20:27:08
User entered 'Day 78'	System	31 Jul 2020 20:27:08

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-10-14T11:43:06', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a00a087c-25db-4178-8da8-2470a1af6f28'	System	14 Oct 2020 15:43:16
User entered 'No (N)'	System	14 Oct 2020 15:43:16

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

Have you been exposed to someone with 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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-10-14T11:43:09', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a00a087c-25db-4178-8da8-2470a1af6f28'	System	14 Oct 2020 15:43:16
User entered 'No (N)'	System	14 Oct 2020 15:43:16

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-10-14T11:43:13', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a00a087c-25db-4178-8da8-2470a1af6f28' User entered '14 Oct 2020 11:43:13'	System	14 Oct 2020 15:43:16
	System	14 Oct 2020 15:43:16



**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	31 Jul 2020 20:27:08
User entered '14 Oct 2020 00:01'	System	31 Jul 2020 20:27:08

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	31 Jul 2020 20:27:08
User entered '18 Oct 2020 23:59'	System	31 Jul 2020 20:27:08

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	31 Jul 2020 20:27:08
User entered 'Day 92'	System	31 Jul 2020 20:27:08

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-10-31T18:56:16', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '49af159d-3414-42a8-bcd9-4879bff199e1' User entered 'No (N)'	System	31 Oct 2020 22:56:25
	System	31 Oct 2020 22:56:25

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

Have you been exposed to someone with 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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-10-31T18:56:05', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '49af159d-3414-42a8-bcd9-4879bff199e1' User entered 'No (N)'	System	31 Oct 2020 22:56:25
	System	31 Oct 2020 22:56:25

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-10-31T18:56:20', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '49af159d-3414-42a8-bcd9-4879bff199e1' User entered '31 Oct 2020 18:56:20'	System	31 Oct 2020 22:56:25
	System	31 Oct 2020 22:56:25

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	31 Jul 2020 20:27:08
User entered '28 Oct 2020 00:01'	System	31 Jul 2020 20:27:08

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	31 Jul 2020 20:27:08
User entered '01 Nov 2020 23:59'	System	31 Jul 2020 20:27:08



**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	31 Jul 2020 20:27:08
User entered 'Day 99'	System	31 Jul 2020 20:27:08

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-06T12:03:57', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a5970e9e-5377-457d-9fab-1040835cc982'	System	06 Nov 2020 17:05:33
User entered 'No (N)'	System	06 Nov 2020 17:05:33

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

Have you been exposed to someone with 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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-06T12:04:00', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a5970e9e-5377-457d-9fab-1040835cc982'	System	06 Nov 2020 17:05:33
User entered 'No (N)'	System	06 Nov 2020 17:05:33

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-06T12:04:03', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a5970e9e-5377-457d-9fab-1040835cc982' User entered '06 Nov 2020 12:04:03'	System	06 Nov 2020 17:05:33
	System	06 Nov 2020 17:05:33

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	31 Jul 2020 20:27:08
User entered '04 Nov 2020 00:01'	System	31 Jul 2020 20:27:08

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	31 Jul 2020 20:27:08
User entered '08 Nov 2020 23:59'	System	31 Jul 2020 20:27:08

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	31 Jul 2020 20:27:08
User entered 'Day 106'	System	31 Jul 2020 20:27:08

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-11T00:01:34', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'dcd7ef02-fc2f-482c-990c-29751bf46c34'	System	11 Nov 2020 05:01:47
User entered 'No (N)'	System	11 Nov 2020 05:01:47



**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

Have you been exposed to someone with 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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-11T00:01:38', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'dcd7ef02-fc2f-482c-990c-29751bf46c34'	System	11 Nov 2020 05:01:47
User entered 'No (N)'	System	11 Nov 2020 05:01:47

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-11T00:01:41', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'dcd7ef02-fc2f-482c-990c-29751bf46c34' User entered '11 Nov 2020 00:01:41'	System	11 Nov 2020 05:01:47
	System	11 Nov 2020 05:01:47

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	31 Jul 2020 20:27:08
User entered '11 Nov 2020 00:01'	System	31 Jul 2020 20:27:08

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	31 Jul 2020 20:27:08
User entered '15 Nov 2020 23:59'	System	31 Jul 2020 20:27:08

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '27 Sep 2020 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '01 Oct 2020 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 11:04:34



**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '04 Oct 2020 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '08 Oct 2020 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '11 Oct 2020 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '15 Oct 2020 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '18 Oct 2020 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '22 Oct 2020 23:59'	System	19 Nov 2020 11:04:34



**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '25 Oct 2020 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '29 Oct 2020 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '01 Nov 2020 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '05 Nov 2020 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '08 Nov 2020 00:01'	System	19 Nov 2020 11:04:34



**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '12 Nov 2020 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '15 Nov 2020 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '19 Nov 2020 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-22T22:18:01', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '08e8a2aa-3b86-4adf-aea8-4116465f7086'	System	23 Nov 2020 03:18:09
User entered 'No (N)'	System	23 Nov 2020 03:18:09

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

Have you been exposed to someone with 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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-22T22:18:03', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '08e8a2aa-3b86-4adf-aea8-4116465f7086'	System	23 Nov 2020 03:18:09
User entered 'No (N)'	System	23 Nov 2020 03:18:09

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-22T22:18:08', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '08e8a2aa-3b86-4adf-aea8-4116465f7086' User entered '22 Nov 2020 22:18:08'	System	23 Nov 2020 03:18:09
	System	23 Nov 2020 03:18:09



**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 11:04:34



**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 11:04:34



**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 11:04:34



**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 11:04:34



**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 11:04:34



**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 11:04:34



**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 11:04:34



**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 11:04:34



**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 11:04:34



**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 11:04:34



**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 11:04:34



**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 11:04:34



**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 11:04:34



**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 11:04:34



**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 11:04:34



**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 11:04:34



**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 11:04:34



**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 11:04:34



**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 11:04:34



**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 11:04:34



**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 11:04:34



**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 11:04:34



**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 11:04:34



**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 11:04:34



**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 11:04:34



**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 11:04:34



**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 11:04:34



**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 11:04:34



**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 11:04:34



**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 11:04:34



**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 11:04:34



**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 11:04:34



**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 11:04:34



**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 11:04:34



**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 11:04:34



**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 11:04:34



**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 11:04:34

**US3022103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:42:00**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 08:42:00

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:24:45
DataPoint Un-verified.	(b) (4), (b) (6)	09 Nov 2020 19:59:11
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:47:01
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	17 Aug 2020 22:55:20
	(b) (4)	

US3022103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:42:00

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:25:30
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Neck pain, LLT: Neck pain - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 22:58:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	17 Aug 2020 22:58:17
Data point term sent to Coder	System	17 Aug 2020 22:57:32
User entered 'NECK PAIN'	Shanice Bennett (b) (4)	17 Aug 2020 22:57:02
	(b) (4)	

**US3022103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:42:00**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:25:33
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	17 Aug 2020 22:57:02
	(b) (4)	



**US3022103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:42:00**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:25:35
User entered 'No (N)'	Shanice Bennett (b) (4)	17 Aug 2020 22:57:02
	(b) (4)	

US3022103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:42:00

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:25:38
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 15:04:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 15:04:01
User entered 'No (N)' reason for change: Data Entry Error	Stella Yoon (b) (4)	31 Aug 2020 15:04:01
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 15:03:56
User entered empty.	Stella Yoon (b) (4)	31 Aug 2020 15:03:56
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:32:29

US3022103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:42:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:25:40
User entered '14 Aug 2020'	Shanice Bennett (b) (4)	17 Aug 2020 22:57:02
	(b) (4)	

**US3022103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:42:00**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:25:42
User entered empty.	Shanice Bennett (b) (4)	17 Aug 2020 22:57:02
	(b) (4)	

**US3022103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:42:00**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 22:57:02

**US3022103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:42:00**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:25:43
User entered 'No (N)'	Shanice Bennett (b) (4)	17 Aug 2020 22:57:02
	(b) (4)	

**US3022103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:42:00**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:25:44
User entered '17 Aug 2020'	Shanice Bennett (b) (4)	17 Aug 2020 22:57:02
	(b) (4)	

**US3022103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:42:00**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:25:47
User entered empty.	Shanice Bennett (b) (4)	17 Aug 2020 22:57:02
	(b) (4)	



**US3022103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:42:00**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 22:57:02

US3022103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:42:00

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:25:49
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Shanice Bennett (b) (4)	17 Aug 2020 22:57:02
	(b) (4)	

US3022103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:42:00

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:25:53
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Aug 2020 22:59:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Aug 2020 22:59:13
User entered 'No (N)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	17 Aug 2020 22:59:13
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Aug 2020 22:57:02
User entered empty.	Shanice Bennett (b) (4)	17 Aug 2020 22:57:02

**US3022103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:42:00**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:25:56
User entered '0'	Shanice Bennett (b) (4)	17 Aug 2020 22:57:02
	(b) (4)	

**US3022103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:42:00**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:25:57
User entered '0'	Shanice Bennett (b) (4)	17 Aug 2020 22:57:02
	(b) (4)	

**US3022103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:42:00**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:25:59
User entered '0'	Shanice Bennett (b) (4)	17 Aug 2020 22:57:02
	(b) (4)	

US3022103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:42:00

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:26:03
User entered empty.	Shanice Bennett (b) (4)	17 Aug 2020 22:57:02
	(b) (4)	

US3022103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:42:00

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:26:05
User entered empty.	Shanice Bennett (b) (4)	17 Aug 2020 22:57:02
	(b) (4)	



**US3022103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:42:00**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:26:07
User entered empty.	Shanice Bennett (b) (4)	17 Aug 2020 22:57:02
	(b) (4)	

**US3022103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:42:00**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:26:09
User entered empty.	Shanice Bennett (b) (4)	17 Aug 2020 22:57:02
	(b) (4)	

US3022103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:42:00

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:26:10
User entered '0'	Shanice Bennett (b) (4)	17 Aug 2020 22:57:02
	(b) (4)	

**US3022103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:42:00**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:26:12
User entered '0'	Shanice Bennett (b) (4)	17 Aug 2020 22:57:02
	(b) (4)	

**US3022103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:42:00**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:26:13
User entered '0'	Shanice Bennett (b) (4)	17 Aug 2020 22:57:02
	(b) (4)	

**US3022103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:42:00**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:26:15
User entered 'Not Related (NOT RELATED)'	Shanice Bennett (b) (4)	17 Aug 2020 22:57:02
	(b) (4)	

**US3022103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:42:00**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:26:17
User entered 'Not Related (NOT RELATED)'	Shanice Bennett (b) (4)	17 Aug 2020 22:57:02
	(b) (4)	

**US3022103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:42:00**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	Shanice Bennett (b) (4) (b) (4)	17 Aug 2020 22:57:02



US3022103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:42:00

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:26:20
User entered '0' reason for change: Data Entry Error	Stella Yoon (b) (4)	31 Aug 2020 15:03:56
	(b) (4)	
User entered '1'	Shanice Bennett (b) (4)	17 Aug 2020 22:57:02
	(b) (4)	

US3022103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:42:00

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:26:22
User entered '1' reason for change: Data Entry Error	Stella Yoon (b) (4)	31 Aug 2020 15:03:56
	(b) (4)	
User entered '0'	Shanice Bennett (b) (4)	17 Aug 2020 22:57:02
	(b) (4)	

**US3022103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:42:00**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:26:25
User entered '0'	Shanice Bennett (b) (4)	17 Aug 2020 22:57:02
	(b) (4)	

**US3022103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:42:00**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:26:27
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Shanice Bennett (b) (4)	17 Aug 2020 22:57:02
	(b) (4)	

**US3022103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:42:00**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:26:29
User entered empty.	Shanice Bennett (b) (4)	17 Aug 2020 22:57:02
	(b) (4)	

**US3022103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:42:00**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:26:31
User entered empty.	Shanice Bennett (b) (4)	17 Aug 2020 22:57:02
	(b) (4)	

**US3022103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:42:00**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Amendment Manager: User entered '0'	System	21 Aug 2020 01:32:32
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:32:29

**US3022103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:42:00**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Amendment Manager: User entered 'I'	System	21 Aug 2020 01:32:32
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:32:29



**US3022103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:42:00**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:32:29

US3022103

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:42:00

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:26:55
User coded data point as SOC: Investigations, HLT: Hepatobiliary investigations, HLT: Liver function analyses, PT: Hepatic enzyme increased, LLT: Elevated liver enzymes - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 22:59:18
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 22:59:18
	(b) (4)	
Data point term sent to Coder	System	17 Aug 2020 22:58:33
User entered 'ELEVATED LIVER ENZYMES'	Shanice Bennett (b) (4)	17 Aug 2020 22:58:32
	(b) (4)	

**US3022103**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 08:42:00**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:26:57
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	17 Aug 2020 22:58:32
	(b) (4)	

**US3022103**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 08:42:00**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:26:59
User entered 'No (N)'	Shanice Bennett (b) (4)	17 Aug 2020 22:58:32
	(b) (4)	

US3022103

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:42:00

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:27:00
User closed query 'Per CDM: Response is required. Please provide.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 16:51:31
Query 'Per CDM: Response is required. Please provide.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 16:27:38
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 16:27:31
User opened query 'Per CDM: Response is required. Please provide.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 18:12:43
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:32:29

US3022103

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:42:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:27:03
User entered '17 Aug 2020'	Shanice Bennett (b) (4)	17 Aug 2020 22:58:32
	(b) (4)	

US3022103

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:42:00

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:27:04
User entered empty.	Shanice Bennett (b) (4)	17 Aug 2020 22:58:32
	(b) (4)	

**US3022103**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 08:42:00**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 22:58:32



**US3022103**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 08:42:00**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:27:07
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	17 Aug 2020 22:58:32
	(b) (4)	

**US3022103**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 08:42:00**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:27:09
User entered empty.	Shanice Bennett (b) (4)	17 Aug 2020 22:58:32
	(b) (4)	

**US3022103**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 08:42:00**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:27:11
User entered empty.	Shanice Bennett (b) (4)	17 Aug 2020 22:58:32
	(b) (4)	

**US3022103**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 08:42:00**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 22:58:32

US3022103

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:42:00

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:27:25
User entered 'Grade 3/Severe (Grade 3/Severe)'	Shanice Bennett (b) (4)	17 Aug 2020 22:58:48
reason for change: Data Entry Error	(b) (4)	
User entered 'Grade 4 (Grade 4)'	Shanice Bennett (b) (4)	17 Aug 2020 22:58:32
	(b) (4)	

US3022103

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:42:00

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:27:29
User closed query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	System	17 Aug 2020 22:58:48
Query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' answered by data change (Site from System).	System	17 Aug 2020 22:58:48
User opened query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	System	17 Aug 2020 22:58:32
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	17 Aug 2020 22:58:32

**US3022103**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 08:42:00**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:27:30
User entered '0'	Shanice Bennett (b) (4)	17 Aug 2020 22:58:32
	(b) (4)	

**US3022103**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 08:42:00**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:27:32
User entered '0'	Shanice Bennett (b) (4)	17 Aug 2020 22:58:32
	(b) (4)	



**US3022103**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 08:42:00**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:27:35
User entered '0'	Shanice Bennett (b) (4)	17 Aug 2020 22:58:32
	(b) (4)	

US3022103

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:42:00

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:27:37
User entered empty.	Shanice Bennett (b) (4)	17 Aug 2020 22:58:32
	(b) (4)	

US3022103

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:42:00

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:27:40
User entered empty.	Shanice Bennett (b) (4)	17 Aug 2020 22:58:32
	(b) (4)	

**US3022103**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 08:42:00**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:27:46
User entered empty.	Shanice Bennett (b) (4)	17 Aug 2020 22:58:32
	(b) (4)	

**US3022103**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 08:42:00**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:27:48
User entered empty.	Shanice Bennett (b) (4)	17 Aug 2020 22:58:32
	(b) (4)	

US3022103

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:42:00

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:27:51
User entered '0'	Shanice Bennett (b) (4)	17 Aug 2020 22:58:32
	(b) (4)	

US3022103

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:42:00

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:27:53
User entered '0'	Shanice Bennett (b) (4)	17 Aug 2020 22:58:32
	(b) (4)	

US3022103

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:42:00

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:27:55
User entered '0'	Shanice Bennett (b) (4)	17 Aug 2020 22:58:32
	(b) (4)	



**US3022103**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 08:42:00**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:27:57
User entered 'Not Related (NOT RELATED)'	Shanice Bennett (b) (4)	17 Aug 2020 22:58:32
	(b) (4)	

**US3022103**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 08:42:00**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:27:59
User entered 'Not Related (NOT RELATED)'	Shanice Bennett (b) (4)	17 Aug 2020 22:58:32
	(b) (4)	

**US3022103**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 08:42:00**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:28:01
User entered 'None (NONE)'	Shanice Bennett (b) (4)	17 Aug 2020 22:58:32
	(b) (4)	

**US3022103**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 08:42:00**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:28:02
User entered 'I'	Shanice Bennett (b) (4)	17 Aug 2020 22:58:32
	(b) (4)	

**US3022103**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 08:42:00**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:28:05
User entered '0'	Shanice Bennett (b) (4)	17 Aug 2020 22:58:32
	(b) (4)	

**US3022103**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 08:42:00**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:28:07
User entered '0'	Shanice Bennett (b) (4)	17 Aug 2020 22:58:32
	(b) (4)	

**US3022103**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 08:42:00**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:28:09
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Shanice Bennett (b) (4)	17 Aug 2020 22:58:32
	(b) (4)	

**US3022103**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 08:42:00**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:28:11
User entered empty.	Shanice Bennett (b) (4)	17 Aug 2020 22:58:32
	(b) (4)	



**US3022103**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 08:42:00**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:28:13
User entered empty.	Shanice Bennett (b) (4)	17 Aug 2020 22:58:32
	(b) (4)	

**US3022103**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 08:42:00**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Amendment Manager: User entered '0'	System	21 Aug 2020 01:32:32
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:32:29

**US3022103**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 08:42:00**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Amendment Manager: User entered 'I'	System	21 Aug 2020 01:32:32
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:32:29

**US3022103**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 08:42:00**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:32:29

**US3022103**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 08:42:00**

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:42:13
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:46:57
User entered	System	15 Sep 2020 14:46:51
'USA-US051-2020-mRNA-1273-P301000004'		
User entered 'New'	(b) (4), (b) (6)	15 Sep 2020 14:46:51

US3022103

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:00

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 01:37:33
User closed query 'Per the source, AE term is spelled Epigastric. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 01:37:32
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Gastrointestinal and abdominal pains (excl oral and throat), PT: Abdominal pain upper, LLT: Epigastric pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Nov 2020 21:46:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Nov 2020 21:46:38
Data point term sent to Coder	System	09 Nov 2020 21:45:25
Query 'Per the source, AE term is spelled Epigastric. Please reconcile. ' answered with 'updated' (Site from CRA).	Shanice Bennett (b) (4) (b) (4)	09 Nov 2020 21:45:20
Coding entries removed.	Shanice Bennett (b) (4) (b) (4)	09 Nov 2020 21:45:14
User entered 'INTERMITTENT Epigastric PAIN' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	09 Nov 2020 21:45:14
User opened query 'Per the source, AE term is spelled Epigastric. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 18:00:36
User closed query 'PV Query: Please provide the final diagnosis/etiology for the epigastric pain, and consider updating event term accordingly.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 20:34:13
Query 'PV Query: Please provide the final diagnosis/etiology for the epigastric pain, and consider updating event term accordingly.' answered with 'unknown' (Site from Safety).	Shanice Bennett (b) (4) (b) (4)	22 Oct 2020 15:37:58
User opened query 'PV Query: Please provide the final diagnosis/etiology for the epigastric pain, and consider updating event term accordingly.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 16:40:36
User closed query 'PV Query: Please provide the final diagnosis/etiology for the epigastric pain, and consider updating event term accordingly. ' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 12:54:06

US3022103

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:00

[Adverse event](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the final diagnosis/etiology for the epigastric pain, and consider updating event term accordingly. ' answered with 'unknown' (Site from Safety).	Shanice Bennett (b) (4)	02 Oct 2020 21:26:15
User opened query 'PV Query: Please provide the final diagnosis/etiology for the epigastric pain, and consider updating event term accordingly. ' (Site from Safety).	(b) (4), (b) (6)	21 Sep 2020 19:36:35
Query 'PV Query: Please consider updating the event term to the final diagnosis or underlying reason for the intermittent epigastric pain.' canceled (Site from Safety).	(b) (4), (b) (6)	21 Sep 2020 19:36:14
User opened query 'PV Query: Please consider updating the event term to the final diagnosis or underlying reason for the intermittent epigastric pain.' (Site from Safety).	(b) (4), (b) (6)	21 Sep 2020 19:34:04
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Gastrointestinal and abdominal pains (excl oral and throat), PT: Abdominal pain upper, LLT: Epigastric pain - version MedDRA\23.0.	Coder Import (b) (4)	15 Sep 2020 19:21:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	15 Sep 2020 19:21:52
Data point term sent to Coder	System	14 Sep 2020 16:50:56
User entered 'INTERMITTENT EIPGASTRIC PAIN'	Shanice Bennett (b) (4)	14 Sep 2020 16:50:30

**US3022103**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 08:42:00**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:34:46
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	14 Sep 2020 16:50:30
	(b) (4)	



**US3022103**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 08:42:00**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:34:49
User entered 'No (N)'	Shanice Bennett (b) (4)	14 Sep 2020 16:50:30
	(b) (4)	

**US3022103**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 08:42:00**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:34:54
User entered 'No (N)'	Shanice Bennett (b) (4)	14 Sep 2020 16:50:30
	(b) (4)	

US3022103

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV query: Start date was reported as 16 Aug 2020 in EDC and in paper SAE form start date of the event was reported as 10 Sep 2020. Please confirm the start date and update EDC accordingly.' (Site from Safety).	(b) (4), (b) (6)	21 Nov 2020 00:36:07
Query 'PV query: Start date was reported as 16 Aug 2020 in EDC and in paper SAE form start date of the event was reported as 10 Sep 2020. Please confirm the start date and update EDC accordingly.' answered with 'chart states 16aug2020' (Site from Safety).	Shanice Bennett (b) (4)	19 Nov 2020 22:34:03
User opened query 'PV query: Start date was reported as 16 Aug 2020 in EDC and in paper SAE form start date of the event was reported as 10 Sep 2020. Please confirm the start date and update EDC accordingly.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 18:47:23
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:34:57
User entered '16 Aug 2020'	Shanice Bennett (b) (4)	14 Sep 2020 16:50:30

US3022103

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:00

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:29:00
User entered empty.	Shanice Bennett (b) (4)	14 Sep 2020 16:50:30
	(b) (4)	

**US3022103**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 08:42:00**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 16:50:30

US3022103

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:00

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:29:05
User closed query 'Per the source, the SAE was resolved on 21Aug2020. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 01:37:41
Query 'Per the source, the SAE was resolved on 21Aug2020. Please reconcile.' answered with 'no sae isn't resolve, i have to contact patient' (Site from CRA).	Shanice Bennett (b) (4)	09 Nov 2020 21:45:36
	(b) (4)	
User opened query 'Per the source, the SAE was resolved on 21Aug2020. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 20:00:37
User closed query 'PV query: Please provide the end date of the event, when available. Please do not respond to this query until the event has ended. ' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 12:54:10
Query 'PV query: Please provide the end date of the event, when available. Please do not respond to this query until the event has ended. ' answered with 'yes' (Site from Safety).	Shanice Bennett (b) (4)	02 Oct 2020 21:26:19
	(b) (4)	
User opened query 'PV query: Please provide the end date of the event, when available. Please do not respond to this query until the event has ended. ' (Site from Safety).	(b) (4), (b) (6)	21 Sep 2020 19:33:24
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	14 Sep 2020 16:50:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:00

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please confirm event stop date as paper SAE form has 14 Sep 2020.' (Site from Safety).	(b) (4), (b) (6)	21 Nov 2020 00:35:52
Query 'PV Query: Please confirm event stop date as paper SAE form has 14 Sep 2020.' answered with 'this is ongoing per chart' (Site from Safety).	Shanice Bennett (b) (4)	19 Nov 2020 22:34:40
User opened query 'PV Query: Please confirm event stop date as paper SAE form has 14 Sep 2020.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 18:47:56
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:29:14
User closed query 'PV query: Please provide the end date of the event, when available. Please leave query open until information is received.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 22:41:22
Query 'PV query: Please provide the end date of the event, when available. Please leave query open until information is received.' answered with 'update hen available ' (Site from Safety).	Shanice Bennett (b) (4)	09 Nov 2020 21:45:46
User opened query 'PV query: Please provide the end date of the event, when available. Please leave query open until information is received.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 12:46:01
User closed query 'PV query: Please provide the end date of the event, when available. Please leave query open until information is received.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 20:34:22
Query 'PV query: Please provide the end date of the event, when available. Please leave query open until information is received.' answered with 'will update as applicable ' (Site from Safety).	Shanice Bennett (b) (4)	22 Oct 2020 15:38:07
User opened query 'PV query: Please provide the end date of the event, when available. Please leave query open until information is received.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 16:37:23
User entered empty.	Shanice Bennett (b) (4)	14 Sep 2020 16:50:30

**US3022103**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 08:42:00**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:29:18
User entered empty.	Shanice Bennett (b) (4)	14 Sep 2020 16:50:30
	(b) (4)	



**US3022103**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 08:42:00**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 16:50:30

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:00

Severity

Audit	User	Time (GMT)
User closed query 'PV Query: Severity was reported as Grade 2/moderate on the SAE paper form. In the EDC severity is denoted as Grade 4. Please confirm or update EDC as needed.' (Site from Safety).	(b) (4), (b) (6)	21 Nov 2020 00:35:49
Query 'PV Query: Severity was reported as Grade 2/moderate on the SAE paper form. In the EDC severity is denoted as Grade 4. Please confirm or update EDC as needed.' answered with 'per chart grade 4' (Site from Safety).	Shanice Bennett (b) (4)	19 Nov 2020 22:34:51
User opened query 'PV Query: Severity was reported as Grade 2/moderate on the SAE paper form. In the EDC severity is denoted as Grade 4. Please confirm or update EDC as needed.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 18:48:05
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 01:37:47
User closed query 'Per the source, the severity was grade 4. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 01:37:45
Query 'Per the source, the severity was grade 4. Please reconcile. ' answered with 'updated' (Site from CRA).	Shanice Bennett (b) (4)	09 Nov 2020 21:45:51
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	09 Nov 2020 21:45:14
User opened query 'Per the source, the severity was grade 4. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 20:35:41
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Shanice Bennett (b) (4)	14 Sep 2020 16:50:30

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:00

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:36:13
Query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' canceled (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 16:42:01
User opened query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 16:41:38
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	14 Sep 2020 16:50:30

**US3022103**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 08:42:00**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:29:29
User entered '0'	Shanice Bennett (b) (4)	14 Sep 2020 16:50:30
	(b) (4)	

**US3022103**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 08:42:00**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:29:31
User entered '0'	Shanice Bennett (b) (4)	14 Sep 2020 16:50:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:00

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:40:31
User closed query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 20:34:33
Query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' answered with 'yes but nothing else is applicable to mark ' (Site from Safety).	Shanice Bennett (b) (4)	22 Oct 2020 15:36:50
User opened query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 16:42:11
User entered 'I'	Shanice Bennett (b) (4)	14 Sep 2020 16:50:30

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:00

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:36:18
User entered '16 Aug 2020'	Shanice Bennett (b) (4)	14 Sep 2020 16:50:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:00

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:36:21
User entered '17 Aug 2020'	Shanice Bennett (b) (4)	14 Sep 2020 16:50:30
	(b) (4)	



**US3022103**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 08:42:00**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:36:24
User entered 'No (N)'	Shanice Bennett (b) (4)	14 Sep 2020 16:50:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:00

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:29:34
DataPoint Un-verified.	(b) (4), (b) (6)	09 Nov 2020 21:02:03
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:40:45
User entered empty.	Shanice Bennett (b) (4)	14 Sep 2020 16:50:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:00

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:29:36
DataPoint Un-verified.	(b) (4), (b) (6)	09 Nov 2020 21:01:56
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:01:46
User entered '0'	Shanice Bennett (b) (4)	14 Sep 2020 16:50:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:00

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:29:38
DataPoint Un-verified.	(b) (4), (b) (6)	09 Nov 2020 21:01:58
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:01:43
User entered '0'	Shanice Bennett (b) (4)	14 Sep 2020 16:50:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:00

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:29:39
DataPoint Un-verified.	(b) (4), (b) (6)	09 Nov 2020 21:01:54
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:01:41
User entered '0'	Shanice Bennett (b) (4)	14 Sep 2020 16:50:30
	(b) (4)	

**US3022103**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 08:42:00**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:37:15
User entered 'Not Related (NOT RELATED)'	Shanice Bennett (b) (4)	14 Sep 2020 16:50:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:00

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User closed query 'Per CDM, re-query: Adverse events starting after the first dose should have a "related" or "not related" selected for relationship to study procedure. Update as appropriate or clarify. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 07:08:41
Query 'Per CDM, re-query: Adverse events starting after the first dose should have a "related" or "not related" selected for relationship to study procedure. Update as appropriate or clarify. ' answered with 'updated' (Site from DM).	Morgan Deal (b) (4)	23 Nov 2020 18:24:29
DataPoint Un-verified.	(b) (4)	
User entered 'Not Related (NOT RELATED)' reason for change: Per Query Resolution	Morgan Deal (b) (4)	23 Nov 2020 18:24:22
User opened query 'Per CDM, re-query: Adverse events starting after the first dose should have a "related" or "not related" selected for relationship to study procedure. Update as appropriate or clarify. ' (Site from DM).	(b) (4)	
User closed query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 18:25:40
Query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' answered with 'due to stress' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 18:25:40
User opened query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	Shanice Bennett (b) (4)	19 Nov 2020 22:35:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 12:34:46
	(b) (4), (b) (6)	09 Nov 2020 20:37:40
User entered 'Not Applicable (NOT APPLICABLE)'	Shanice Bennett (b) (4)	14 Sep 2020 16:50:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:00

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'PV query: Action taken with the study drug was reported as none in EDC. However, in paper SAE form it was reported as dose delayed , please confirm the action taken and update accordingly.' (Site from Safety).	(b) (4), (b) (6)	21 Nov 2020 00:35:59
Query 'PV query: Action taken with the study drug was reported as none in EDC. However, in paper SAE form it was reported as dose delayed , please confirm the action taken and update accordingly.' answered with 'per chart this is correct' (Site from Safety).	Shanice Bennett (b) (4)	19 Nov 2020 22:35:32
User opened query 'PV query: Action taken with the study drug was reported as none in EDC. However, in paper SAE form it was reported as dose delayed , please confirm the action taken and update accordingly.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 18:47:41
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:29:43
User closed query 'PV query: A 2nd dose of study drug was never administered. However, the action taken with study drug as updated to NONE. Please confirm if the study drug was withdrawn. If so, please update EDC with the appropriate action taken.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 22:41:32
Query 'PV query: A 2nd dose of study drug was never administered. However, the action taken with study drug as updated to NONE. Please confirm if the study drug was withdrawn. If so, please update EDC with the appropriate action taken.' answered with 'subject is awaiting answer on if she can receive 2nd dose or not' (Site from Safety).	Shanice Bennett (b) (4)	09 Nov 2020 21:46:11
User opened query 'PV query: A 2nd dose of study drug was never administered. However, the action taken with study drug as updated to NONE. Please confirm if the study drug was withdrawn. If so, please update EDC with the appropriate action taken.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 16:41:02



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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:00

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'PV query: Please confirm if the 2nd dose of study drug was administered. If not, please consider assessing action taken with study drug as withdrawn. ' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 12:54:17
Query 'PV query: Please confirm if the 2nd dose of study drug was administered. If not, please consider assessing action taken with study drug as withdrawn. ' answered with 'updated' (Site from Safety).	Shanice Bennett (b) (4)	02 Oct 2020 21:26:51
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4)	02 Oct 2020 21:26:45
User opened query 'PV query: Please confirm if the 2nd dose of study drug was administered. If not, please consider assessing action taken with study drug as withdrawn. ' (Site from Safety).	(b) (4), (b) (6)	21 Sep 2020 19:36:48
User entered 'Dose Delayed (DOSE DELAYED)'	Shanice Bennett (b) (4)	14 Sep 2020 16:50:30

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:00

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:38:10
User closed query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 16:37:31
Query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' answered with 'updated' (Site from DM).	Shanice Bennett (b) (4)	02 Oct 2020 21:27:25
User entered '0' reason for change: Data Entry Error	(b) (4)	02 Oct 2020 21:27:20
User opened query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 11:16:14
User entered '1'	Shanice Bennett (b) (4)	14 Sep 2020 16:50:30

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:00

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:38:12
User entered '1' reason for change: Data Entry Error	Shanice Bennett (b) (4)	02 Oct 2020 21:27:20
	(b) (4)	
User entered '0'	Shanice Bennett (b) (4)	14 Sep 2020 16:50:30
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 08:42:00**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:01:16
User entered '0'	Shanice Bennett (b) (4)	14 Sep 2020 16:50:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:00

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:29:56
User closed query 'Per the source, the event was resolved 21Aug2020. Please review. ' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 01:37:57
User closed query 'PV query: Please provide the final outcome of the event, when available. Please leave query open until information is received.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 22:41:46
Query 'Per the source, the event was resolved 21Aug2020. Please review. ' answered with 'updated' (Site from CRA).	Shanice Bennett (b) (4)	09 Nov 2020 21:46:22
Query 'PV query: Please provide the final outcome of the event, when available. Please leave query open until information is received.' answered with 'correct ' (Site from Safety).	Shanice Bennett (b) (4)	09 Nov 2020 21:46:18
User opened query 'Per the source, the event was resolved 21Aug2020. Please review. ' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 20:39:19
User opened query 'PV query: Please provide the final outcome of the event, when available. Please leave query open until information is received.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 12:46:24
User closed query 'PV query: Please provide the final outcome of the event, when available. Please leave query open until information is received.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 20:35:05
Query 'PV query: Please provide the final outcome of the event, when available. Please leave query open until information is received.' answered with 'will update as applicable ' (Site from Safety).	Shanice Bennett (b) (4)	22 Oct 2020 15:37:47
User opened query 'PV query: Please provide the final outcome of the event, when available. Please leave query open until information is received.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 16:39:36
User closed query 'PV query: Please provide the final outcome of the event, when available. Please do not respond to this query until the event has ended.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 12:54:21

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:00

[Outcome](#)

Audit	User	Time (GMT)
Query 'PV query: Please provide the final outcome of the event, when available. Please do not respond to this query until the event has ended.' answered with 'not resolved ' (Site from Safety).	Shanice Bennett (b) (4)	02 Oct 2020 21:27:36
User opened query 'PV query: Please provide the final outcome of the event, when available. Please do not respond to this query until the event has ended.' (Site from Safety).	(b) (4), (b) (6)	21 Sep 2020 19:33:49
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Shanice Bennett (b) (4)	14 Sep 2020 16:50:30

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:00

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:31:51
DataPoint Un-verified.	(b) (4), (b) (6)	09 Nov 2020 20:39:24
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:39:22
User entered empty.	Shanice Bennett (b) (4)	14 Sep 2020 16:50:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:00

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:32:21
User closed query 'PV query: Please provide a redacted discharge summary when available.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 22:42:07
Query 'PV query: Please provide a redacted discharge summary when available.' answered with 'Will send medical records. ' (Site from Safety).	Shanice Bennett (b) (4)	09 Nov 2020 21:46:53
User opened query 'PV query: Please provide a redacted discharge summary when available.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 12:46:53
User closed query 'PV Query: Please assess if the pericardial effusion at the base of the heart met AE/ SAE reporting criteria. If so please report. If not please state as such.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 20:35:10
Query 'PV Query: Please assess if the pericardial effusion at the base of the heart met AE/ SAE reporting criteria. If so please report. If not please state as such.' answered with 'unknown ' (Site from Safety).	Shanice Bennett (b) (4)	22 Oct 2020 15:37:36
User opened query 'PV Query: Please assess if the pericardial effusion at the base of the heart met AE/ SAE reporting criteria. If so please report. If not please state as such.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 16:40:02
User closed query 'PV Query: Please report if the patient had a COVID test while hospitalized. If yes, please provide result and date.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 12:54:26
User closed query 'PV Query: Please assess if the pericardial effusion at the base of the heart met AE/ SAE reporting criteria. If so please report. If not please state as such. ' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 12:54:24
Query 'PV Query: Please assess if the pericardial effusion at the base of the heart met AE/ SAE reporting criteria. If so please report. If not please state as such. ' answered with 'pending records' (Site from Safety).	Shanice Bennett (b) (4)	02 Oct 2020 21:27:50
Query 'PV Query: Please report if the patient had a COVID test while hospitalized. If yes, please provide result and date.' answered with 'no' (Site from Safety).	Shanice Bennett (b) (4)	02 Oct 2020 21:27:45



US3022103

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 08:42:00

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please report if the patient had a COVID test while hospitalized. If yes, please provide result and date.' (Site from Safety).	(b) (4), (b) (6)	21 Sep 2020 19:34:22
User opened query 'PV Query: Please assess if the pericardial effusion at the base of the heart met AE/SAE reporting criteria. If so please report. If not please state as such. ' (Site from Safety).	(b) (4), (b) (6)	21 Sep 2020 19:32:47
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	14 Sep 2020 16:51:15
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	14 Sep 2020 16:51:15
User entered 'PENDING MEDICAL RECORDS.' reason for change: Data Entry Error	Shanice Bennett (b) (4)	14 Sep 2020 16:51:15
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	14 Sep 2020 16:50:30
User entered empty.	Shanice Bennett (b) (4)	14 Sep 2020 16:50:30

**US3022103**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 08:42:00**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Sep 2020 16:50:30

**US3022103**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 08:42:00**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Sep 2020 16:50:30

**US3022103**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 08:42:00**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Sep 2020 16:50:30

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 08:42:00

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:32:38
User entered 'Yes (Y)'	Stella Yoon (b) (4)	31 Jul 2020 21:10:11
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:42:00

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:33:28
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Jul 2020 21:13:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	31 Jul 2020 21:12:02
User entered 'Fluticasone'	Stella Yoon (b) (4)	31 Jul 2020 21:11:01
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:42:00

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:33:30
User entered 'No (N)'	Stella Yoon (b) (4)	31 Jul 2020 21:11:01
	(b) (4)	

**US3022103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 08:42:00**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:33:33
User entered 'seasonal allergies'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:11:01



US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:42:00

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:33:35
User entered '50'	Stella Yoon (b) (4)	31 Jul 2020 21:11:01
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:42:00

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:33:37
User entered 'ug (ug)'	Stella Yoon (b) (4)	31 Jul 2020 21:11:01
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:42:00

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:33:38
User entered empty.	Stella Yoon (b) (4)	31 Jul 2020 21:11:01
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:42:00

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:33:41
User entered 'twice daily (BID)'	Stella Yoon (b) (4)	31 Jul 2020 21:11:01
	(b) (4)	

**US3022103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 08:42:00**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:33:43
User entered empty.	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:11:01

**US3022103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 08:42:00**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:33:45
User entered 'Nasal (NASAL)'	Stella Yoon (b) (4)	31 Jul 2020 21:11:01
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:42:00

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:33:49
User entered empty.	Stella Yoon (b) (4)	31 Jul 2020 21:11:01
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:42:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:33:51
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	03 Aug 2020 13:07:19
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ongoing' (Site from System).	Stella Yoon (b) (4)	31 Jul 2020 21:11:50
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	31 Jul 2020 21:11:01
User entered 'un UNK 2003'	Stella Yoon (b) (4)	31 Jul 2020 21:11:01



US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:42:00

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:33:53
User entered '0'	Stella Yoon (b) (4)	31 Jul 2020 21:11:01
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:42:00

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:33:55
User entered 'Yes (Y)'	Stella Yoon (b) (4)	31 Jul 2020 21:11:01
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:42:00

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:33:58
User entered empty.	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:11:01

**US3022103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 08:42:00**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:34:00
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:11:01

**US3022103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 08:42:00**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	31 Jul 2020 21:11:01

**US3022103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 08:42:00**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Jul 2020 21:11:01

**US3022103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 08:42:00**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Jul 2020 21:11:01

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:42:00

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:34:17
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIFUNGALS FOR DERMATOLOGICAL USE, ATC: ANTIFUNGALS FOR TOPICAL USE, ATC: IMIDAZOLE AND TRIAZOLE DERIVATIVES, PRODUCT: KETOCONAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 05:35:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 05:35:41
Data point term sent to Coder	System	31 Aug 2020 15:03:23
User entered 'ketoconazole' reason for change: Data Entry Error	Stella Yoon (b) (4) (b) (4)	31 Aug 2020 15:03:13
Coding entries removed.	Stella Yoon (b) (4) (b) (4)	31 Aug 2020 15:02:44
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIFUNGALS FOR DERMATOLOGICAL USE, ATC: ANTIFUNGALS FOR TOPICAL USE, ATC: IMIDAZOLE AND TRIAZOLE DERIVATIVES, PRODUCT: KETOCONAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Aug 2020 11:25:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Aug 2020 11:25:05
Data point term sent to Coder	System	31 Jul 2020 21:12:02
User entered 'ketoconazole'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:11:37



US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:42:00

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:34:19
User entered 'No (N)'	Stella Yoon (b) (4)	31 Jul 2020 21:11:37
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:42:00

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:34:20
User closed query "'Per DM CLR: Please update the indication to reflect the location/type of OTOMYCOSIS (right, left or bilateral). Please reconcile with the AE and Med History eCRFs as appropriate.	(b) (4), (b) (6)	01 Sep 2020 06:28:33
' (Site from DM).		
Query "'Per DM CLR: Please update the indication to reflect the location/type of OTOMYCOSIS (right, left or bilateral). Please reconcile with the AE and Med History eCRFs as appropriate.	Stella Yoon (b) (4)	31 Aug 2020 15:03:18
	(b) (4)	
' answered with 'updated' (Site from DM).		
User entered 'ONYCHOMYCOSIS bilateral' reason for change: Data Entry Error	Stella Yoon (b) (4)	31 Aug 2020 15:02:44
	(b) (4)	
User opened query "'Per DM CLR: Please update the indication to reflect the location/type of OTOMYCOSIS (right, left or bilateral). Please reconcile with the AE and Med History eCRFs as appropriate.	(b) (4), (b) (6)	31 Aug 2020 13:58:24
' (Site from DM).		
User entered 'otomycosis'	Stella Yoon (b) (4)	31 Jul 2020 21:11:37
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:42:00

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:34:22
User closed query ' Per DM CLR: Please note, 15 g pertains to drug tube weight. So please verify if the DOSE to reflect the single dose taken by the subject in # of applications (e.g., Dose=1, If dose unit is Other, specify = applications) would be more appropriate recording. Update eCRF as appropriate." ' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 06:30:04
Query ' Per DM CLR: Please note, 15 g pertains to drug tube weight. So please verify if the DOSE to reflect the single dose taken by the subject in # of applications (e.g., Dose=1, If dose unit is Other, specify = applications) would be more appropriate recording. Update eCRF as appropriate." ' answered with 'updated' (Site from DM).	Stella Yoon (b) (4)	31 Aug 2020 15:03:24
User entered '200-400' reason for change: Data Entry Error	(b) (4)	31 Aug 2020 15:03:13
User opened query ' Per DM CLR: Please note, 15 g pertains to drug tube weight. So please verify if the DOSE to reflect the single dose taken by the subject in # of applications (e.g., Dose=1, If dose unit is Other, specify = applications) would be more appropriate recording. Update eCRF as appropriate." ' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 13:58:32
User entered '15'	Stella Yoon (b) (4)	31 Jul 2020 21:11:37
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:42:00

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:34:29
User entered 'mg (mg)' reason for change: Data Entry Error	Stella Yoon (b) (4)	31 Aug 2020 15:03:13
	(b) (4)	
User entered 'g (g)'	Stella Yoon (b) (4)	31 Jul 2020 21:11:37
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:42:00

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:34:41
User entered empty.	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:11:37

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:42:00

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:34:45
User entered 'once daily (QD)'	Stella Yoon (b) (4)	31 Jul 2020 21:11:37
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:42:00

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:34:50
User entered empty.	Stella Yoon (b) (4)	31 Jul 2020 21:11:37
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:42:00

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:34:51
User closed query 'Per DM CLR: The dose provided does not correspond to a TOPICAL formulation of this medication. Please verify if "Oral" is a more appropriate recording. Update eCRF as appropriate. Otherwise, provide clarification in query response.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 16:37:04
Query 'Per DM CLR: The dose provided does not correspond to a TOPICAL formulation of this medication. Please verify if "Oral" is a more appropriate recording. Update eCRF as appropriate. Otherwise, provide clarification in query response.'	(b) (4), (b) (6)	02 Oct 2020 20:30:29
answered with 'this is correct' (Site from DM).		
User opened query 'Per DM CLR: The dose provided does not correspond to a TOPICAL formulation of this medication. Please verify if "Oral" is a more appropriate recording. Update eCRF as appropriate. Otherwise, provide clarification in query response.'	(b) (4), (b) (6)	16 Sep 2020 05:28:00
(Site from DM).		
User entered 'Topical (TOPICAL)'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:11:37



US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:42:00

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:34:53
User entered empty.	Stella Yoon (b) (4)	31 Jul 2020 21:11:37
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:42:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:34:55
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	03 Aug 2020 13:07:23
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ongoing' (Site from System).	Stella Yoon (b) (4)	31 Jul 2020 21:11:45
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	
User entered 'un UNK 2018'	System	31 Jul 2020 21:11:37
	Stella Yoon (b) (4)	31 Jul 2020 21:11:37
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:42:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:34:58
User entered '0'	Stella Yoon (b) (4)	31 Jul 2020 21:11:37
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:42:00

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:35:00
User entered 'Yes (Y)'	Stella Yoon (b) (4)	31 Jul 2020 21:11:37
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:42:00

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:35:02
User entered empty.	Stella Yoon (b) (4)	31 Jul 2020 21:11:37
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:42:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:35:04
User entered 'No (N)'	Stella Yoon (b) (4)	31 Jul 2020 21:11:37
	(b) (4)	

**US3022103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 08:42:00**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Jul 2020 21:11:37

**US3022103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 08:42:00**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Jul 2020 21:11:37



**US3022103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 08:42:00**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Jul 2020 21:11:37

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:42:00

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:35:15
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: OTHER DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), PRODUCT: SUCRALFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 07:05:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 07:05:15
Data point term sent to Coder	System	17 Aug 2020 22:54:29
User entered 'SUCRALFATE'	Shanice Bennett (b) (4) (b) (4)	17 Aug 2020 22:53:34

**US3022103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 08:42:00**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:35:20
User entered 'No (N)'	Shanice Bennett (b) (4)	17 Aug 2020 22:53:34
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:42:00

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:35:21
User entered 'ABDOMINAL PAIN'	Shanice Bennett (b) (4)	17 Aug 2020 22:53:34
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:42:00

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:35:24
User entered 'I'	Shanice Bennett (b) (4)	17 Aug 2020 22:53:34
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:42:00

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:35:26
User entered 'g (g)'	Shanice Bennett (b) (4)	17 Aug 2020 22:53:34
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:42:00

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:35:32
User entered empty.	Shanice Bennett (b) (4)	17 Aug 2020 22:53:34
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:42:00

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:35:34
User entered 'once daily (QD)'	Shanice Bennett (b) (4)	17 Aug 2020 22:53:34
	(b) (4)	



US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:42:00

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:35:36
User entered empty.	Shanice Bennett (b) (4)	17 Aug 2020 22:53:34
	(b) (4)	

**US3022103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 08:42:00**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:35:38
User entered 'Oral (ORAL)'	Shanice Bennett (b) (4)	17 Aug 2020 22:53:34
	(b) (4)	

**US3022103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 08:42:00**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:35:40
User entered empty.	Shanice Bennett (b) (4)	17 Aug 2020 22:53:34
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:42:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 02:19:25
User closed query 'Per the source, the start date was 16Aug2020. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:19:23
Query 'Per the source, the start date was 16Aug2020. Please reconcile.' answered with 'updated date' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 23:32:12
DataPoint Un-verified.	(b) (4), (b) (6)	13 Nov 2020 23:31:16
User entered '16 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Nov 2020 23:31:16
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:35:48
User opened query 'Per the source, the start date was 16Aug2020. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 20:31:38
User entered '17 Aug 2020'	Shanice Bennett (b) (4) (b) (4)	17 Aug 2020 22:53:34

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:42:00

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:35:50
User entered '0'	Shanice Bennett (b) (4)	17 Aug 2020 22:53:34
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:42:00

[Ongoing?](#)

Audit	User	Time (GMT)
Query 'Re-query: Per the source, the SAE has an end date of 21Aug2020. Please confirm if medication is ongoing.' answered with 'per chart this is still ongoing' (Site from CRA).	Shanice Bennett (b) (4)	19 Nov 2020 22:36:03
User opened query 'Re-query: Per the source, the SAE has an end date of 21Aug2020. Please confirm if medication is ongoing.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:19:59
User closed query 'Per the source, the SAE has an end date of 21Aug2020. Please confirm if medication is ongoing.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:19:59
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Nov 2020 23:33:12
Query 'Per the source, the SAE has an end date of 21Aug2020. Please confirm if medication is ongoing.' answered with 'updated ' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 23:32:19
DataPoint Un-verified.	(b) (4), (b) (6)	13 Nov 2020 23:31:16
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Nov 2020 23:31:16
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:35:58
User opened query 'Per the source, the SAE has an end date of 21Aug2020. Please confirm if medication is ongoing.' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 20:31:02
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	17 Aug 2020 22:53:34

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:42:00

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	13 Nov 2020 23:33:12
DataPoint Un-verified.	(b) (4), (b) (6)	13 Nov 2020 23:31:16
User entered '21 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Nov 2020 23:31:16
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:36:01
User entered empty.	Shanice Bennett (b) (4)	17 Aug 2020 22:53:34
	(b) (4)	

**US3022103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 08:42:00**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:36:03
User entered 'No (N)'	Shanice Bennett (b) (4)	17 Aug 2020 22:53:34
	(b) (4)	



**US3022103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 08:42:00**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 22:53:34

**US3022103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 08:42:00**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 22:53:34

**US3022103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 08:42:00**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 22:53:34

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:42:00

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:36:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 07:22:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 07:22:21
Data point term sent to Coder	System	17 Aug 2020 22:54:30
User entered 'PANTOPRAZOLE'	Shanice Bennett (b) (4) (b) (4)	17 Aug 2020 22:54:13

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:42:00

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:36:19
User entered 'No (N)'	Shanice Bennett (b) (4)	17 Aug 2020 22:54:13
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:42:00

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:36:21
User entered 'ABDOMINAL PAIN'	Shanice Bennett (b) (4)	17 Aug 2020 22:54:13
	(b) (4)	

**US3022103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 08:42:00**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:36:24
User entered '40'	Shanice Bennett (b) (4)	17 Aug 2020 22:54:13
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:42:00

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:36:26
User entered 'mg (mg)'	Shanice Bennett (b) (4)	17 Aug 2020 22:54:13
	(b) (4)	



US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:42:00

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:36:27
User entered empty.	Shanice Bennett (b) (4)	17 Aug 2020 22:54:13
	(b) (4)	

**US3022103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 08:42:00**

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Shanice Bennett (b) (4) (b) (4)	17 Aug 2020 22:54:13

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:42:00

If frequency is Other, specify

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	17 Aug 2020 22:54:13

**US3022103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 08:42:00**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:36:34
User entered 'Oral (ORAL)'	Shanice Bennett (b) (4)	17 Aug 2020 22:54:13
	(b) (4)	

**US3022103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 08:42:00**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:36:36
User entered empty.	Shanice Bennett (b) (4)	17 Aug 2020 22:54:13
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:42:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 02:20:16
User closed query 'Per the source, the start date was 16Aug2020. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:20:15
Query 'Per the source, the start date was 16Aug2020. Please reconcile. ' answered with 'updated ' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 23:33:49
DataPoint Un-verified.	(b) (4), (b) (6)	13 Nov 2020 23:33:37
User entered '16 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Nov 2020 23:33:37
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:36:37
User opened query 'Per the source, the start date was 16Aug2020. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 20:24:27
User entered '17 Aug 2020'	Shanice Bennett (b) (4) (b) (4)	17 Aug 2020 22:54:13

**US3022103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 08:42:00**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:36:39
User entered '0'	Shanice Bennett (b) (4)	17 Aug 2020 22:54:13
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:42:00

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Per the source, the SAE has an end date of 21Aug2020. Please confirm if medication is ongoing.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:20:39
Query 'Per the source, the SAE has an end date of 21Aug2020. Please confirm if medication is ongoing.' answered with 'still ongoing ' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 23:33:57
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:36:41
User opened query 'Per the source, the SAE has an end date of 21Aug2020. Please confirm if medication is ongoing.' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 20:29:30
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	17 Aug 2020 22:54:13



US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:42:00

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:36:44
User entered empty.	Shanice Bennett (b) (4)	17 Aug 2020 22:54:13
	(b) (4)	

**US3022103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 08:42:00**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:36:46
User entered 'No (N)'	Shanice Bennett (b) (4)	17 Aug 2020 22:54:13
	(b) (4)	

**US3022103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 08:42:00**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 22:54:13

**US3022103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 08:42:00**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 22:54:13

**US3022103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 08:42:00**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 22:54:13

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:42:00

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:36:53
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 22:56:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 22:56:15
Data point term sent to Coder	System	17 Aug 2020 22:55:31
User entered 'ADVIL'	Shanice Bennett (b) (4) (b) (4)	17 Aug 2020 22:55:14

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:42:00

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:36:55
User entered 'No (N)'	Shanice Bennett (b) (4)	17 Aug 2020 22:55:14
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:42:00

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:36:57
User closed query 'Per DM CLR: The corresponding AE recorded (AE# 1) does not show 'Concomitant Medication' =Yes. Please reconcile and update applicable eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 10:57:15
Query 'Per DM CLR: The corresponding AE recorded (AE# 1) does not show 'Concomitant Medication' =Yes. Please reconcile and update applicable eCRFs as appropriate. ' answered with 'updated' (Site from DM).	Stella Yoon (b) (4) (b) (4)	31 Aug 2020 15:04:15
User opened query 'Per DM CLR: The corresponding AE recorded (AE# 1) does not show 'Concomitant Medication' =Yes. Please reconcile and update applicable eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 13:58:55
User entered 'NECK PAIN'	Shanice Bennett (b) (4) (b) (4)	17 Aug 2020 22:55:14



US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:42:00

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:36:59
User entered '400'	Shanice Bennett (b) (4)	17 Aug 2020 22:55:14
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:42:00

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:37:01
User entered 'mg (mg)'	Shanice Bennett (b) (4)	17 Aug 2020 22:55:14
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:42:00

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:37:03
User entered empty.	Shanice Bennett (b) (4)	17 Aug 2020 22:55:14
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:42:00

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:37:09
User entered 'three times daily (TID)'	Shanice Bennett (b) (4)	17 Aug 2020 22:55:14
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:42:00

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:37:13
User entered empty.	Shanice Bennett (b) (4)	17 Aug 2020 22:55:14
	(b) (4)	

**US3022103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 08:42:00**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:37:15
User entered 'Oral (ORAL)'	Shanice Bennett (b) (4)	17 Aug 2020 22:55:14
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:42:00

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:37:17
User entered empty.	Shanice Bennett (b) (4)	17 Aug 2020 22:55:14
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:42:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:37:19
User entered '15 Aug 2020'	Shanice Bennett (b) (4)	17 Aug 2020 22:55:14
	(b) (4)	



**US3022103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 08:42:00**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:37:21
User entered '0'	Shanice Bennett (b) (4)	17 Aug 2020 22:55:14
	(b) (4)	

**US3022103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 08:42:00**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:37:22
User entered 'No (N)'	Shanice Bennett (b) (4)	17 Aug 2020 22:55:14
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:42:00

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:37:24
User entered '16 Aug 2020'	Shanice Bennett (b) (4)	17 Aug 2020 22:55:14
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:42:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:37:25
User entered 'No (N)'	Shanice Bennett (b) (4)	17 Aug 2020 22:55:14
	(b) (4)	

**US3022103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 08:42:00**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	17 Aug 2020 22:55:14

**US3022103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 08:42:00**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 22:55:14

**US3022103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 08:42:00**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 22:55:14

**US3022103**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 26 Nov 2020 08:42:00**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	17 Sep 2020 16:39:50



**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:14:29
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered		
'USA-US051-2020-MRNA-1273-P301000004'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:10:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Yes (Y)'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:14:31
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:14:34
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:10:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Yes (Y)'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:14:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:14:41
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:14:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	System	15 Sep 2020 14:46:51



**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:10:15
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Paul'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:10:13
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Bradley'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:10:11
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered '340 Eisenhower Dr.'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:10:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Savannah'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:10:07
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'GA'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:10:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered '31406'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:10:01
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:54:35
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:12:20
User entered 'US' (non-conformant).	System	15 Sep 2020 14:48:03

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	24 Nov 2020 12:38:14
User entered '4'	System	10 Nov 2020 22:29:03
User entered '3'	System	23 Oct 2020 20:35:29
User entered '2'	System	05 Oct 2020 12:54:42
User entered '1'	System	15 Sep 2020 14:48:03



**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:14:29
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered		
'USA-US051-2020-MRNA-1273-P301000004'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:10:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Yes (Y)'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:14:31
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:14:34
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:10:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Yes (Y)'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:14:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:14:41
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:14:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	System	15 Sep 2020 14:46:51



**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:10:15
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Paul'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:10:13
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Bradley'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:10:11
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered '340 Eisenhower Dr.'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:10:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Savannah'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:10:07
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'GA'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:10:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered '31406'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:10:01
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:54:35
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:12:20
User entered 'US' (non-conformant).	System	15 Sep 2020 14:48:03

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	24 Nov 2020 12:38:14
User entered '4'	System	10 Nov 2020 22:29:03
User entered '3'	System	23 Oct 2020 20:35:29
User entered '2'	System	05 Oct 2020 12:54:42
User entered '1'	System	15 Sep 2020 14:48:03



**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form (1)**

**Generated On: 26 Nov 2020 08:42:00**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '15/Sep/2020 10:48'	System	15 Sep 2020 14:48:03

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 08:42:00

**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)	05 Oct 2020 12:54:35
User entered 'I'	(b) (4), (b) (6)	15 Sep 2020 14:48:03

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:14:29
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered		
'USA-US051-2020-MRNA-1273-P301000004'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:10:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Yes (Y)'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:14:31
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:14:34
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:10:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Yes (Y)'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:14:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	System	15 Sep 2020 14:46:51



**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:14:41
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:14:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:10:15
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Paul'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:10:13
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Bradley'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:10:11
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered '340 Eisenhower Dr.'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:10:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Savannah'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:10:07
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'GA'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:10:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered '31406'	System	15 Sep 2020 14:46:51



**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:10:01
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:54:35
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:12:20
User entered 'US' (non-conformant).	System	15 Sep 2020 14:48:03

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	24 Nov 2020 12:38:14
User entered '4'	System	10 Nov 2020 22:29:03
User entered '3'	System	23 Oct 2020 20:35:29
User entered '2'	System	05 Oct 2020 12:54:42
User entered '1'	System	15 Sep 2020 14:48:03

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form (2)**

**Generated On: 26 Nov 2020 08:42:00**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '05/Oct/2020 08:54'	System	05 Oct 2020 12:54:42

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 08:42:00

**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)	23 Oct 2020 20:35:18
User entered 'I'	(b) (4), (b) (6)	05 Oct 2020 12:54:42

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:14:29
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered		
'USA-US051-2020-MRNA-1273-P301000004'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:10:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Yes (Y)'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:14:31
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:14:34
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	System	15 Sep 2020 14:46:51



**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:10:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Yes (Y)'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:14:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:14:41
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:14:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:10:15
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Paul'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:10:13
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Bradley'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:10:11
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered '340 Eisenhower Dr.'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:10:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Savannah'	System	15 Sep 2020 14:46:51



**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:10:07
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'GA'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:10:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered '31406'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:10:01
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:54:35
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:12:20
User entered 'US' (non-conformant).	System	15 Sep 2020 14:48:03

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	24 Nov 2020 12:38:14
User entered '4'	System	10 Nov 2020 22:29:03
User entered '3'	System	23 Oct 2020 20:35:29
User entered '2'	System	05 Oct 2020 12:54:42
User entered '1'	System	15 Sep 2020 14:48:03

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form (3)**

**Generated On: 26 Nov 2020 08:42:00**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '23/Oct/2020 20:35'	System	23 Oct 2020 20:35:29

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 08:42:00

**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)	24 Nov 2020 12:38:05
User entered 'I'	(b) (4), (b) (6)	23 Oct 2020 20:35:29

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:14:29
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered		
'USA-US051-2020-MRNA-1273-P301000004'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:10:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Yes (Y)'	System	15 Sep 2020 14:46:51



**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:14:31
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:14:34
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:10:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Yes (Y)'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:14:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:14:41
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:14:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:10:15
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Paul'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:10:13
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Bradley'	System	15 Sep 2020 14:46:51



**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:10:11
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered '340 Eisenhower Dr.'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:10:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Savannah'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:10:07
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'GA'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:10:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered '31406'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:10:01
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:54:35
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:12:20
User entered 'US' (non-conformant).	System	15 Sep 2020 14:48:03

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	24 Nov 2020 12:38:14
User entered '4'	System	10 Nov 2020 22:29:03
User entered '3'	System	23 Oct 2020 20:35:29
User entered '2'	System	05 Oct 2020 12:54:42
User entered '1'	System	15 Sep 2020 14:48:03

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form (4)**

**Generated On: 26 Nov 2020 08:42:00**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '10/Nov/2020 17:29'	System	10 Nov 2020 22:29:03

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 08:42:00

**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)	24 Nov 2020 12:38:05
User entered 'I'	(b) (4), (b) (6)	10 Nov 2020 22:29:03



**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:14:29
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered		
'USA-US051-2020-MRNA-1273-P301000004'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:10:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Yes (Y)'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:14:31
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:14:34
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:10:22
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Yes (Y)'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:14:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:14:41
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:14:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	System	15 Sep 2020 14:46:51



**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:10:15
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Paul'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:10:13
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Bradley'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:10:11
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered '340 Eisenhower Dr.'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:10:09
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Savannah'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:10:07
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'GA'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:10:05
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered '31406'	System	15 Sep 2020 14:46:51

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:10:01
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:54:35
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:12:20
User entered 'US' (non-conformant).	System	15 Sep 2020 14:48:03

**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 08:42:00**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	24 Nov 2020 12:38:14
User entered '4'	System	10 Nov 2020 22:29:03
User entered '3'	System	23 Oct 2020 20:35:29
User entered '2'	System	05 Oct 2020 12:54:42
User entered '1'	System	15 Sep 2020 14:48:03



**US3022103**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000004**

**Form: Safety Report Form (5)**

**Generated On: 26 Nov 2020 08:42:00**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '24/Nov/2020 07:38'	System	24 Nov 2020 12:38:14

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 08:42:00

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User entered 'I'	(b) (4), (b) (6)	24 Nov 2020 12:38:14