

US3342199 (Prod: Tekton Research- Austin)

Generated By: (b) (6)

Generated On: 26 Nov 2020 10:59:33

All time stamps listed in this document are displayed in GMT

**US3342199**

**Form: Participant Creation**

**Generated On: 26 Nov 2020 10:59:33**

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[Participant ID](#)

US3342199

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

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US3342199

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:59:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:59:33

Date of Birth (MMM yyyy)	(b) (6) 1961
Age	59
Age Units	YEARS
Age (Derived)	59
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:59:33

Date of Informed Consent ( <i>dd MMM yyyy</i> )	4 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input checked="" type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:59:33

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:59:33

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:59:33

Condition	CANCER OF THE KIDNEY (ENCAPSULATED TUMOR)
Start date (dd MMM yyyy)	UN JUN 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	24 AUG 2019
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	AUG 2019
Stop Year (derived)	2019



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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:59:33

Condition	TUMOR REMOVAL RIGHT KIDNEY
Start date (dd MMM yyyy)	24 AUG 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	24 AUG 2019
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2019
Start Year (derived)	2019
Stop Month and Year (derived)	AUG 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:59:33

Condition	HERPES SIMPLEX VIRUS TYPE 1
Start date (dd MMM yyyy)	24 AUG 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:59:33

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1985
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 1985
Start Year (derived)	1985
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:59:33

Condition	INSOMNIA
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)	_____

US3342199

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:59:33

Condition	HEMOCHROMATOSIS
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: Vital Signs

Generated On: 26 Nov 2020 10:59:33

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	4 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	13:58 (24 HR)
Vital Signs Date and Time (derived)	4 SEP 2020 13:58
Height ( <i>xxx.x</i> )	179.0 cm
Weight ( <i>xxx.x</i> )	87.2 kg
BMI ( <i>xxx.x</i> )	27.21513 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:59:33

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

4 SEP 2020

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

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:33

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

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**Specify**

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

**No Risk Identified** False

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

**Resides in Multi-family dwelling** (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>	False
<b>Specify</b>	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:59:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:59:33

What was the date of randomization? (dd MMM yyyy) 04 SEP 2020

What was the participant's randomization number? 111835

In what Cohort was the participant enrolled?   
 >=18 and <65 years and not at risk ☒   
 >=18 and <65 years and at risk ☐   
 >=65 years ☐

If participant is considered at risk, please check all that apply (If any are checked as Yes, please ensure the actual condition is recorded on the Medical History form)

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma) Yes ☐ No ☒

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes ☐ No ☒

Severe obesity (body mass index > or = 40kg/m2) Yes ☐ No ☒

Diabetes (Type I, Type 2, or gestational) Yes ☐ No ☒

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☐

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 26 Nov 2020 10:59:33**

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:33

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	4 SEP 2020
Time of assessment (00:00-23:59)	13:59 (24 HR)
Vital Signs Date and Time (derived)	4 SEP 2020 13:59
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:33

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	4 SEP 2020
Time of assessment (00:00-23:59)	16:00 (24 HR)
Vital Signs Date and Time (derived)	4 SEP 2020 16:00
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	149 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:59:33

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:59:33

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 4 SEP 2020

What was the treatment time? (00:00-23:59) 15:28 (24 HR)

Treatment Date and Time (derived) 4 SEP 2020 15:28

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

What was the frequency of the study treatment dosing? ONCE

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



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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:59:33

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	4 SEP 2020
Collection time ( <i>00:00-23:59</i> )	15:02 (24 HR)
Collection date and time (derived)	4 SEP 2020 15:02

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:59:33

Collection date (dd MMM yyyy)			4 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:04	4 SEP 2020 15:04
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:59:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒  
No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

04 SEP 2020 16:02

PC Open Date & Time

04 SEP 2020 15:48

PC Close Date & Time

04 SEP 2020 18:18

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.1 °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	04 SEP 2020 21:16
PC Open Date & Time	04 SEP 2020 19:13
PC Close Date & Time	05 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 22:46

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.1 °F
Was any <b>MEDICATION TAKEN today for pain or fever?</b>	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	06 SEP 2020 12:01
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:59:33

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**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 21:24

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:59:33

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 18:25

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:59:33

---

**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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 22:53

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:59:33

---

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 12:06

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 16:03

PC Open Date & Time

04 SEP 2020 15:48

PC Close Date & Time

04 SEP 2020 18:18

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 21:17

PC Open Date & Time

04 SEP 2020 19:13

PC Close Date & Time

05 SEP 2020 11:59

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 22:44

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

06 SEP 2020 12:00

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

07 SEP 2020 21:24

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59



US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 18:26

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 22:53

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

10 SEP 2020 12:06

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3342199

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

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

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3342199

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:59:33

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 16:03
PC Open Date & Time	04 SEP 2020 15:48
PC Close Date & Time	04 SEP 2020 18:18

US3342199

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3342199

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:59:33

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 21:18
PC Open Date & Time	04 SEP 2020 19:13
PC Close Date & Time	05 SEP 2020 11:59

US3342199

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒



US3342199

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:59:33

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 22:44
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3342199

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

DAY 3

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3342199

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:59:33

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

US3342199

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3342199

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:59:33

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 21:24
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3342199

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

DAY 5

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3342199

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:59:33

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 18:26
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3342199

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

DAY 6

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒



US3342199

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:59:33

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 22:53
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3342199

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

DAY 7

**HEADACHE**

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3342199

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:59:33

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

US3342199

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

None ☒

**HEADACHE**

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 ☐

PC Time Stamp 11 SEP 2020 13:33

PC Open Date & Time 11 SEP 2020 12:00

PC Close Date & Time 12 SEP 2020 11:59

US3342199

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 26 Nov 2020 10:59:33

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	11 SEP 2020 13:34
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3342199

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:33

Was Contact Attempted?

Yes ☒

No ☐

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

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3342199

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342199

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:33

Was Contact Attempted?

Yes ☒

No ☐

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

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3342199

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342199

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:33

Was Contact Attempted?

Yes ☒

No ☐

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

28 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3342199

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342199

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:59:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3342199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:33

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	1 OCT 2020
Time of assessment (00:00-23:59)	15:19 (24 HR)
Vital Signs Date and Time (derived)	1 OCT 2020 15:19
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3342199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:33

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	1 OCT 2020
Time of assessment (00:00-23:59)	16:36 (24 HR)
Vital Signs Date and Time (derived)	1 OCT 2020 16:36
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3342199

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:59:33

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

1 OCT 2020

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

US3342199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:59:33

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 1 OCT 2020

What was the treatment time? (00:00-23:59) 16:04 (24 HR)

Treatment Date and Time (derived) 1 OCT 2020 16:04

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



US3342199

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:59:33

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	1 OCT 2020
Collection time ( <i>00:00-23:59</i> )	15:51 (24 HR)
Collection date and time (derived)	1 OCT 2020 15:51

US3342199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:59:33

Collection date ( <i>dd MMM yyyy</i> )			1 OCT 2020
Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:53	1 OCT 2020 15:53
Nasopharyngeal Swab 2	No		

US3342199

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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

01 OCT 2020 16:39

PC Open Date & Time

01 OCT 2020 16:24

PC Close Date & Time

01 OCT 2020 18:54

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.2 °F

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

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

PC Time Stamp	01 OCT 2020 20:42
PC Open Date & Time	01 OCT 2020 19:49
PC Close Date & Time	02 OCT 2020 11:59

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:59:33

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**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

97.1 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

02 OCT 2020 12:00

---

PC Open Date & Time

02 OCT 2020 12:00

---

PC Close Date & Time

03 OCT 2020 11:59

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US3342199

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:59:33

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**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 OCT 2020 12:10

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:59:33

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**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

98.1 °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

04 OCT 2020 20:38

---

PC Open Date & Time

04 OCT 2020 12:00

---

PC Close Date & Time

05 OCT 2020 11:59

---



US3342199

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:59:33

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 OCT 2020 13:18

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:59:33

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**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

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

06 OCT 2020 20:33

---

PC Open Date & Time

06 OCT 2020 12:00

---

PC Close Date & Time

07 OCT 2020 11:59

---

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☐  
No ☐

Please record your **TEMPERATURE in °F**

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 07 OCT 2020 12:00

PC Close Date & Time 08 OCT 2020 11:59

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

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

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 OCT 2020 16:39

PC Open Date & Time

01 OCT 2020 16:24

PC Close Date & Time

01 OCT 2020 18:54

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

01 OCT 2020 20:42

PC Open Date & Time

01 OCT 2020 19:49

PC Close Date & Time

02 OCT 2020 11:59

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

02 OCT 2020 12:01

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

03 OCT 2020 12:11

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

04 OCT 2020 20:38

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59



US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

05 OCT 2020 13:18

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

06 OCT 2020 20:33

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

DAY 7

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3342199

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

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

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3342199

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:59:33

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

No ☒

Yes ☐

PC Time stamp	01 OCT 2020 16:40
PC Open Date & Time	01 OCT 2020 16:24
PC Close Date & Time	01 OCT 2020 18:54

US3342199

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3342199

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:59:33

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

No ☒

Yes ☐

PC Time stamp	01 OCT 2020 20:43
PC Open Date & Time	01 OCT 2020 19:49
PC Close Date & Time	02 OCT 2020 11:59

US3342199

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒



US3342199

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:59:33

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

US3342199

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

DAY 3

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3342199

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:59:33

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

US3342199

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3342199

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:59:33

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 20:39
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3342199

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

DAY 5

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3342199

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:59:33

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 13:19
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3342199

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:59:33

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒



US3342199

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:59:33

Yes <input type="checkbox"/>	
PC Time stamp	06 OCT 2020 20:33
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3342199

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

**DAY 7**

**HEADACHE**

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☐

US3342199

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:59:33

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

US3342199

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:33

Was Contact Attempted?

Yes ☒

No ☐

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

8 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3342199

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342199

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:33

Was Contact Attempted?

Yes ☒

No ☐

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

16 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3342199

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342199

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:33

Was Contact Attempted?

Yes ☒

No ☐

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

23 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3342199

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342199

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:59:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3342199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:33

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	28 OCT 2020
Time of assessment ( <i>00:00-23:59</i> )	14:06 (24 HR)
Vital Signs Date and Time (derived)	28 OCT 2020 14:06
Temperature ( <i>xxx.x</i> )	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	60 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	90 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3342199

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:59:33

Was the physical examination performed?

Yes ☐  
No ☒

Date of examination (dd MMM yyyy)

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

US3342199

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:59:33

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	28 OCT 2020
Collection time ( <i>00:00-23:59</i> )	14:47 (24 HR)
Collection date and time (derived)	28 OCT 2020 14:47

US3342199

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 NOV 2020 12:01:09

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

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



**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

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[Patient Cloud Open Date & Time](#)

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01 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

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05 NOV 2020 23:59

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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

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[Patient Cloud Open Date & Time](#)

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08 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

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12 NOV 2020 23:59

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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

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

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 NOV 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 NOV 2020 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

DAY 82

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 NOV 2020 17:18:27

Patient Cloud Open Date & Time

22 NOV 2020 00:01

Patient Cloud Close Date & Time

26 NOV 2020 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

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[Patient Cloud Open Date & Time](#)

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29 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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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 DEC 2020 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	20 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 DEC 2020 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

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

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	27 DEC 2020 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	31 DEC 2020 23:59
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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

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

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

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[Patient Cloud Open Date & Time](#)

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10 JAN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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14 JAN 2021 23:59

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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

DAY 138

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

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

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[Patient Cloud Open Date & Time](#)

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24 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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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

DAY 152

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

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	31 JAN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	04 FEB 2021 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

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

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

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[Patient Cloud Open Date & Time](#)

07 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 FEB 2021 23:59

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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

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

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

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[Patient Cloud Open Date & Time](#)

14 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

18 FEB 2021 23:59

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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

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[Patient Cloud Open Date & Time](#)

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21 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

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25 FEB 2021 23:59

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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

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[Patient Cloud Open Date & Time](#)

28 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

04 MAR 2021 23:59

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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

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[Patient Cloud Open Date & Time](#)

07 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 MAR 2021 23:59

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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

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[Patient Cloud Open Date & Time](#)

14 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

18 MAR 2021 23:59

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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

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

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

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[Patient Cloud Open Date & Time](#)

21 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

25 MAR 2021 23:59

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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

DAY 208

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

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

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

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

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

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

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

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

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

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[Patient Cloud Open Date & Time](#)

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28 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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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

DAY 215

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

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

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[Patient Cloud Open Date & Time](#)

04 APR 2021 00:01

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[Patient Cloud Close Date & Time](#)

08 APR 2021 23:59

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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

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

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

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[Patient Cloud Open Date & Time](#)

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18 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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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

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

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	02 MAY 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 MAY 2021 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

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[Patient Cloud Open Date & Time](#)

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09 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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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

DAY 257

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

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

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

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

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

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

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

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

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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



US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

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[Patient Cloud Open Date & Time](#)

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23 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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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

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

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

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[Patient Cloud Open Date & Time](#)

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30 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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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

DAY 278

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

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

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[Patient Cloud Open Date & Time](#)

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06 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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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

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

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

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[Patient Cloud Open Date & Time](#)

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13 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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17 JUN 2021 23:59

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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

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

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

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

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[Patient Cloud Open Date & Time](#)

20 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

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

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

DAY 306

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

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

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[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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



US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

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[Patient Cloud Open Date & Time](#)

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01 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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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

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[Patient Cloud Open Date & Time](#)

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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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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	15 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	19 AUG 2021 23:59
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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

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

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

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

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[Patient Cloud Open Date & Time](#)

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22 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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26 AUG 2021 23:59

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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

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

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

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[Patient Cloud Open Date & Time](#)

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29 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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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

DAY 369

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

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

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[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

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[Patient Cloud Open Date & Time](#)

12 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

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

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

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

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

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[Patient Cloud Open Date & Time](#)

26 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

TIMEPOINT	DAY 397
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

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[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

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

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

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[Patient Cloud Open Date & Time](#)

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10 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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14 OCT 2021 23:59

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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

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

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	24 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	28 OCT 2021 23:59
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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

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[Patient Cloud Open Date & Time](#)

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31 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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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

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

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

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[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

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[Patient Cloud Open Date & Time](#)

14 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

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[Patient Cloud Open Date & Time](#)

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21 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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25 NOV 2021 23:59

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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

DAY 453

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

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	28 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	02 DEC 2021 23:59



US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

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[Patient Cloud Open Date & Time](#)

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12 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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16 DEC 2021 23:59

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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

DAY 474

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

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

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

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	26 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 DEC 2021 23:59



US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

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

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

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[Patient Cloud Open Date & Time](#)

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02 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 JAN 2022 23:59

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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

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[Patient Cloud Open Date & Time](#)

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09 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 JAN 2022 23:59

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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

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

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

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

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

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

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

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[Patient Cloud Open Date & Time](#)

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23 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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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	30 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	03 FEB 2022 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

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

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

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

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[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

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

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

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[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

DAY 537

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

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

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

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

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

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

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

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

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	20 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 FEB 2022 23:59



US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

DAY 544

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

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

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[Patient Cloud Open Date & Time](#)

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27 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 MAR 2022 23:59

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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

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

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

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

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

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

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

DAY 565

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

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

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[Patient Cloud Open Date & Time](#)

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20 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 MAR 2022 23:59

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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

TIMEPOINT

DAY 572

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

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

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

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

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

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

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

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

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

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[Patient Cloud Open Date & Time](#)

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27 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 MAR 2022 23:59

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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

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

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

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	03 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	07 APR 2022 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

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

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

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

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[Patient Cloud Open Date & Time](#)

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10 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 APR 2022 23:59

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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

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

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

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 APR 2022 23:59



US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	24 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 APR 2022 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

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[Patient Cloud Open Date & Time](#)

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01 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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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

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

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

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[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

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[Patient Cloud Open Date & Time](#)

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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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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

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

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

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[Patient Cloud Open Date & Time](#)

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29 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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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

DAY 642

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

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

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[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

DAY 649

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

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 JUN 2022 23:59



US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

DAY 656

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

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

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[Patient Cloud Open Date & Time](#)

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19 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 JUN 2022 23:59

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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

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

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

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	26 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 JUN 2022 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	03 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	07 JUL 2022 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

TIMEPOINT

DAY 677

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

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

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

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

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

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

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

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

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 JUL 2022 23:59



US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

DAY 684

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

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 JUL 2022 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

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[Patient Cloud Open Date & Time](#)

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24 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 JUL 2022 23:59

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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

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[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

DAY 705

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

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

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[Patient Cloud Open Date & Time](#)

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07 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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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

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

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	14 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	18 AUG 2022 23:59
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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

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

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

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[Patient Cloud Open Date & Time](#)

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28 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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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

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[Patient Cloud Open Date & Time](#)

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04 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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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 SEP 2022 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

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

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	18 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 SEP 2022 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	25 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 SEP 2022 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

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

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

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[Patient Cloud Open Date & Time](#)

02 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	09 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 OCT 2022 23:59

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

**TIMEPOINT**

DAY 775

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

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

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

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	23 OCT 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	27 OCT 2022 23:59
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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

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

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

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[Patient Cloud Open Date & Time](#)

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30 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 NOV 2022 23:59

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US3342199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:33

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3342199**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	06 NOV 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	10 NOV 2022 23:59

US3342199

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:33

Was Contact Attempted?

Yes ☒

No ☐

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

23 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3342199

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3342199**

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

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:59:33**

Was Contact Attempted? Yes ☐  
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

**US3342199**

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

**Form: Continuing**

**Generated On: 26 Nov 2020 10:59:33**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3342199

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:59:33

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

**US3342199**

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

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

**Generated On: 26 Nov 2020 10:59:33**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3342199

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:59:33

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

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US3342199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:33

AEID	USA-US203-2020-MRNA-1273-P30 1000002
Adverse event	ACUTE FOCAL COLITIS
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)	13 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	25 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	13 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	15 SEP 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)	337 of 1850

US3342199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:33

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

US3342199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:33

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SUBJECT WENT TO HOSPITAL  
ON 13SEP2020 FOR ABDOMINAL  
PAIN AND FEVER. ADMITTED,  
CT SCAN DONE, DX COLITIS.  
GIVEN ANTIBIOTICS.  
RELEASED FROM HOSPITAL ON  
15SEP2020. SUBJECT WENT TO  
HOSPITAL ON 13SEP2020 FOR  
ABDOMINAL PAIN AND FEVER.  
ADMITTED, CT SCAN DONE, DX  
COLITIS. GIVEN ANTIBIOTICS.  
RELEASED FROM HOSPITAL ON  
15SEP2020. CT OF  
ABDOMEN/PELVIC SHOWED  
3CM SEGMENT OF  
CIRCUMFERENTIAL BOWEL  
WALL THICKENING IN THE  
SIGMOID COLON WITH  
SIGNIFICANT PERISEROSAL  
INFLAMMATORY CHANGES  
ALONG ITS MESENTERIC SIDE,  
WORRISOME FOR  
MALIGNANCY. DIAGNOSTIC  
CONSIDERATIONS ALSO  
INCLUDE FOCAL COLITIS. CBC  
LABS SHOW ELEVATED WBC  
AT 14.4 THOU/CU MM ON DAY  
OF ADMITTANCE 9/13/2020,  
BACK TO NORMAL VALUES OF  
9.3 AND 7.4 THOU/CU MM ON  
9/14/2020 AND 9/15/2020  
RESPECTIVELY. RBC LEVELS  
LOW AT 4.05, 3.75 AND 3.52  
MLLL/CU MM; HGB 13.4, 12.4,  
11.8 G/DL, HCT 38.3, 36.0, 34.6  
PERCENT, MCV HIGH AT 94.6,  
96.0, 98.3 FL, MCH HIGH AT 33.1,

US3342199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:33

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33,1, 33.5 PG, ON 9/13/2020,  
9/14/2020, AND 9/15/2020.  
DIFFERENTIAL PANEL SHOW  
HIGH NEUTRO AUTO 76.8 AND  
69.8 PERCENT, AND LYMPH  
AUTO LOW AT 13.5 AND 18.7  
PERCENT, ON 9/13/2020 AND  
9/15/2020. UA ALL IN NORMAL  
RANGE ON 9/13/2020. ROUTINE  
CHEMISTRY SHOWED HIGH  
GLUCOSE ON 9/13/2020 AT  
118MG/DL. GLUCOSE LEVELS  
WERE 98 AND 92 MG/DL ON  
9/14/2020 AND 9/15/2020.  
SARSCOV2 TESTING DONE ON  
/13/2020, TARGET NUCLEIC  
ACIDS NOT DETECTED.

---

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

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US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:59:33

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

Yes ☒

No ☐

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

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US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:59:33

Name of Medication	ACYCLOVIR
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HERPES SIMPLEX VIRUS TYPE 1
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 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 checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:59:33

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		24 AUG 2015
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)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:59:33

Name of Medication	PSEUDOEPHEDRINE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	SEASONAL ALLERGIES
Dose per administration	60
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 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 checked="" 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"/>

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:59:33

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 1985
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:59:33

Name of Medication	METRONIDAZOLE
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	AE ACUTE FOCAL COLITIS
Dose per administration	500
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input checked="" type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:59:33

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		13 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 SEP 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"/>

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:59:33

Name of Medication	CIPROFLOXACIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	AE ACUTE FOCAL COLITIS
Dose per administration	500
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 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 checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:59:33

Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	13 SEP 2020
Start date completely unknown	False
Ongoing?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 24 SEP 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 <input type="checkbox"/> 803 <input type="checkbox"/> 804 <input checked="" type="checkbox"/>

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:59:33

Name of Medication	NAPROXEN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HEADACHE
Dose per administration	220
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 type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:59:33

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)		06 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy)		06 SEP 2020
<hr/>		
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
<hr/>		
Separate Dosage Number (derived)		<input type="text"/>
Interval Dosage Unit Number (derived)		<input type="text"/>
Interval Dosage Definition (derived)		802 <input type="checkbox"/>
		803 <input type="checkbox"/>
		804 <input type="checkbox"/>



US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:59:33

Name of Medication	ACETAMINOPHEN-CODEINE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	AE ACUTE FOCAL COLITIS
Dose per administration	300/30
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 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 checked="" 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"/>

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:59:33

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		13 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:59:33

Name of Medication	ZOLPIDEM
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	INSOMNIA
Dose per administration	5
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 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 checked="" 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"/>

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:59:33

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<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)	<input type="text"/>	
Interval Dosage Unit Number (derived)	<input type="text"/>	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:59:33

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

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:59:33

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		14 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		14 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:59:33

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

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:59:33

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" 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)		13 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:59:33

Name of Medication	FAMOTIDINE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	AE ACUTE FOCAL COLITIS
Dose per administration	UNKNOWN
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	UNKNOWN
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" 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"/>

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:59:33

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		13 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:59:33

Name of Medication	ALLOPURINOL
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	MAINTAINENCE DRUG FOR POST PARTIAL NEPHRECTOMY
Dose per administration	100
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:59:33

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN SEP 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		UN FEB 2020
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"/>

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:59:33

Name of Medication	YEARLY FLU VACCINE
Prophylaxis	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Indication	YEARLY FLU PREVENTION
Dose per administration	.5
Dose unit	mg <input type="radio"/>
	ug <input type="radio"/>
	mL <input checked="" 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 type="radio"/>
	four times daily <input type="radio"/>
	every other day <input type="radio"/>
	every week <input type="radio"/>
	every month <input type="radio"/>
	as needed <input type="radio"/>
	once <input checked="" type="radio"/>
	unknown <input type="radio"/>
	other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/>
	Topical <input type="radio"/>
	Subcutaneous <input type="radio"/>
	Transdermal <input type="radio"/>
	Intraocular <input type="radio"/>
	Intramuscular <input checked="" type="radio"/>

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:59:33

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		16 OCT 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 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3342199

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 10:59:33

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3342199

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 10:59:33

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
13 SEP 2020	CT SCAN ABDOMEN/PELVIS	Adverse Event	
15 SEP 2020	CBC LABS	Adverse Event	
13 SEP 2020	CBC LABS	Adverse Event	
15 SEP 2020	ROUTINE CHEMISTRY	Adverse Event	
14 SEP 2020	ROUTINE CHEMISTRY	Adverse Event	
13 SEP 2020	ROUTINE CHEMISTRY	Adverse Event	
25 SEP 2020	COLONOSCOPY	Adverse Event	



US3342199

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:59:33

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

US3342199

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:59:33

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Other ☐

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

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:33

SAEID	USA-US203-2020-MRNA-1273-P301000002
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	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:59:33

SAEID	USA-US203-2020-MRNA-1273-P301000002
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	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	20/SEP/2020 14:32
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

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:59:33

SAEID	USA-US203-2020-MRNA-1273-P301000002
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	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	29/SEP/2020 10:49
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 10:59:33

SAEID	USA-US203-2020-MRNA-1273-P301000002
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	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	01/OCT/2020 08:09
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

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 10:59:33

SAEID	USA-US203-2020-MRNA-1273-P301000002
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	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	02/OCT/2020 12:31
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

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 10:59:33

SAEID	USA-US203-2020-MRNA-1273-P301000002
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	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	12/OCT/2020 14:17
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True



Audit

US3342199 (Prod: Tekton Research- Austin)

**US3342199**

**Form: Participant Creation**

**Generated On: 26 Nov 2020 10:59:33**

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3342199'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	04 Sep 2020 19:09:27

**US3342199**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:59:33**

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 19:59:23

US3342199

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:59:33

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:47
User entered '04 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 19:09:28

**US3342199**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:59:33**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:47
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	04 Sep 2020 19:59:23

**US3342199**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:59:33**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	04 Sep 2020 19:59:23

US3342199

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:59:33

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:54
User entered (b) (6) 1961'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 19:09:29

**US3342199**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:59:33**

[Age](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:54
User entered '59'	(b) (4), (b) (6)	04 Sep 2020 20:01:41



**US3342199**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:59:33**

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	04 Sep 2020 20:01:41

**US3342199**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:59:33**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '59'	System	04 Sep 2020 20:02:01

US3342199

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:59:33

[Sex](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:54
User entered 'Male (M)'	(b) (4), (b) (6)	04 Sep 2020 20:01:41

**US3342199**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:59:33**

[Ethnicity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:54
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	04 Sep 2020 20:01:41

**US3342199**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:59:33**

[White](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:54
User entered 'I'	(b) (4), (b) (6)	04 Sep 2020 20:01:41

**US3342199**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:59:33**

[Black](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:54
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 20:01:41

**US3342199**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:59:33**

[Asian](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:54
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 20:01:41

**US3342199**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:59:33**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:54
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 20:01:41



**US3342199**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:59:33**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:54
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 20:01:41

**US3342199**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:59:33**

[Other](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:54
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 20:01:41

US3342199

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:59:33

[If race is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:54
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:01:41

**US3342199**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:59:33**

[Unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:54
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 20:01:41

**US3342199**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:59:33**

[Not reported](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:45:54
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 20:01:41

**US3342199**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:59:33**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:46:11
User entered '4 Sep 2020'	(b) (4), (b) (6)	04 Sep 2020 20:02:01

**US3342199**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:59:33**

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

Audit	User	Time (GMT)
User entered 'Sep 2020'	System	04 Sep 2020 20:02:01

**US3342199**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:59:33**

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

Audit	User	Time (GMT)
User entered '2020'	System	04 Sep 2020 20:02:01



**US3342199**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:59:33**

[Protocol Version](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:46:11
User entered 'Amendment 3 (3)'	(b) (4), (b) (6)	04 Sep 2020 20:02:01

**US3342199**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:59:33**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:46:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 20:02:01

**US3342199**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:59:33**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:46:11
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:02:01

**US3342199**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:59:33**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:46:11
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:02:01

**US3342199**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:59:33**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:46:11
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 20:02:01

US3342199

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:59:33

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:46:11
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 19:09:28

**US3342199**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:59:33**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Sep 2020 20:02:07

**US3342199**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 26 Nov 2020 10:59:33**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:46:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 20:02:07



US3342199

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:59:33

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:46:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 20:05:41

US3342199

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:59:33

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:46:41
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Renal and urinary tract neoplasms malignant and unspecified, HLT: Renal neoplasms malignant, PT: Renal cancer, LLT: Renal cancer - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 22:59:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 22:59:46
Data point term sent to Coder	System	04 Sep 2020 20:36:01
User entered 'cancer of the kidney (encapsulated tumor)'	(b) (4), (b) (6)	04 Sep 2020 20:35:17

**US3342199**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:59:33**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:46:41
User entered 'un Jun 2019'	(b) (4), (b) (6)	04 Sep 2020 20:35:17

**US3342199**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:59:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:46:41
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 20:35:17

**US3342199**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:59:33**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:46:41
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 20:35:17

**US3342199**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:59:33**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:46:41
User entered '24 Aug 2019'	(b) (4), (b) (6)	04 Sep 2020 20:35:17

US3342199

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:59:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:46:41
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 20:35:17

**US3342199**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:59:33**

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

Audit	User	Time (GMT)
User entered 'Jun 2019'	System	04 Sep 2020 20:35:17



**US3342199**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:59:33**

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

Audit	User	Time (GMT)
User entered '2019'	System	04 Sep 2020 20:35:17

**US3342199**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:59:33**

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

Audit	User	Time (GMT)
User entered 'Aug 2019'	System	04 Sep 2020 20:35:17

**US3342199**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:59:33**

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

Audit	User	Time (GMT)
User entered '2019'	System	04 Sep 2020 20:35:17

US3342199

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:59:33

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:46:41
User coded data point as SOC: Surgical and medical procedures, HLGT: Renal and urinary tract therapeutic procedures, HLT: Renal therapeutic procedures, PT: Renal tumour excision, LLT: Renal tumor excision - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Sep 2020 07:29:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Sep 2020 07:29:46
Data point term sent to Coder	System	04 Sep 2020 20:36:01
User entered 'tumor removal right kidney'	(b) (4), (b) (6)	04 Sep 2020 20:35:50

**US3342199**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:59:33**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:46:41
User entered '24 Aug 2019'	(b) (4), (b) (6)	04 Sep 2020 20:35:50

**US3342199**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:59:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:46:41
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 20:35:50

**US3342199**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:59:33**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:46:41
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 20:35:50

**US3342199**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:59:33**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:46:41
User entered '24 Aug 2019'	(b) (4), (b) (6)	04 Sep 2020 20:35:50



**US3342199**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:59:33**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:46:41
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 20:35:50

**US3342199**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:59:33**

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

Audit	User	Time (GMT)
User entered 'Aug 2019'	System	04 Sep 2020 20:35:50

**US3342199**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:59:33**

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

Audit	User	Time (GMT)
User entered '2019'	System	04 Sep 2020 20:35:50

**US3342199**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:59:33**

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

Audit	User	Time (GMT)
User entered 'Aug 2019'	System	04 Sep 2020 20:35:50

**US3342199**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:59:33**

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

Audit	User	Time (GMT)
User entered '2019'	System	04 Sep 2020 20:35:50

US3342199

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:59:33

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:46:41
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Herpes simplex, LLT: Herpes simplex type I - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 20:37:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 20:37:46
Data point term sent to Coder	System	04 Sep 2020 20:37:03
User entered 'herpes simplex virus type 1'	(b) (4), (b) (6)	04 Sep 2020 20:36:32

**US3342199**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:59:33**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:46:41
User entered '24 Aug 2015'	(b) (4), (b) (6)	04 Sep 2020 20:36:32

**US3342199**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:59:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:46:41
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 20:36:32



**US3342199**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:59:33**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:46:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 20:36:32

**US3342199**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:59:33**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:46:41
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:36:32

**US3342199**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:59:33**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:46:41
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 20:36:32

**US3342199**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:59:33**

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

Audit	User	Time (GMT)
User entered 'Aug 2015'	System	04 Sep 2020 20:36:32

**US3342199**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:59:33**

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

Audit	User	Time (GMT)
User entered '2015'	System	04 Sep 2020 20:36:32

**US3342199**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:59:33**

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

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 20:36:32

**US3342199**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:59:33**

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

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 20:36:32

US3342199

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:59:33

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:46:41
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) (b) (4)	04 Sep 2020 20:38:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 20:38:20
Data point term sent to Coder	System	04 Sep 2020 20:37:04
User entered 'seasonal allergies'	(b) (4), (b) (6)	04 Sep 2020 20:36:50



US3342199

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:59:33

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:46:41
User entered 'un UNK 1985'	(b) (4), (b) (6)	04 Sep 2020 20:36:50

US3342199

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:59:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:46:41
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 20:36:50

**US3342199**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:59:33**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:46:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 20:36:50

**US3342199**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:59:33**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:46:41
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:36:50

**US3342199**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:59:33**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:46:41
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 20:36:50

**US3342199**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:59:33**

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

Audit	User	Time (GMT)
User entered 'Jan 1985'	System	04 Sep 2020 20:36:50

**US3342199**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:59:33**

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

Audit	User	Time (GMT)
User entered '1985'	System	04 Sep 2020 20:36:50

**US3342199**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:59:33**

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

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 20:36:50



**US3342199**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:59:33**

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

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 20:36:50

US3342199

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:59:33

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:46:41
User coded data point as SOC: Psychiatric disorders, HLT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 21:05:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	09 Oct 2020 21:05:42
Data point term sent to Coder	System	09 Oct 2020 20:25:45
User entered 'INSOMNIA'	Eileen Euperio (b) (4)	09 Oct 2020 20:25:10
	(b) (4)	

**US3342199**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:59:33**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:46:41
User entered 'UN UNK 2018'	Eileen Euperio (b) (4)	09 Oct 2020 20:25:10
	(b) (4)	

**US3342199**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:59:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:46:41
User entered '0'	Eileen Euperio (b) (4)	09 Oct 2020 20:25:10
	(b) (4)	

**US3342199**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:59:33**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:46:41
User entered 'Yes (Y)'	Eileen Euperio (b) (4)	09 Oct 2020 20:25:10
	(b) (4)	

**US3342199**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:59:33**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:46:41
User entered empty.	Eileen Euperio (b) (4)	09 Oct 2020 20:25:10
	(b) (4)	

**US3342199**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:59:33**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:46:41
User entered '0'	Eileen Euperio (b) (4)	09 Oct 2020 20:25:10
	(b) (4)	

**US3342199**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:59:33**

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	09 Oct 2020 20:25:10



**US3342199**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:59:33**

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

Audit	User	Time (GMT)
User entered '2018'	System	09 Oct 2020 20:25:10

**US3342199**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:59:33**

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

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 20:25:10

**US3342199**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:59:33**

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

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 20:25:10

US3342199

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:59:33

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:46:41
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Iron and trace metal metabolism disorders, HLT: Iron excess, PT: Haemochromatosis, LLT: Hemochromatosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 21:06:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 21:06:31
Data point term sent to Coder	System	09 Oct 2020 20:25:46
User entered 'HEMOCHROMATOSIS'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:25:25

**US3342199**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:59:33**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:46:41
User entered 'UN UNK 2018'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:25:25

**US3342199**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:59:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:46:41
User entered '0'	Eileen Euperio (b) (4)	09 Oct 2020 20:25:25
	(b) (4)	

**US3342199**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:59:33**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:46:41
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:25:25

**US3342199**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:59:33**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:46:41
User entered empty.	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:25:25



**US3342199**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:59:33**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:46:41
User entered '0'	Eileen Euperio (b) (4)	09 Oct 2020 20:25:25
	(b) (4)	

**US3342199**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:59:33**

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	09 Oct 2020 20:25:25

**US3342199**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:59:33**

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

Audit	User	Time (GMT)
User entered '2018'	System	09 Oct 2020 20:25:25

**US3342199**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:59:33**

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

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 20:25:25

**US3342199**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:59:33**

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

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 20:25:25

US3342199

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:47:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 20:06:29

US3342199

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:47:00
User entered '4 Sep 2020'	(b) (4), (b) (6)	04 Sep 2020 20:06:29

**US3342199**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:59:33**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:47:00
User entered '13:58'	(b) (4), (b) (6)	04 Sep 2020 20:06:29



**US3342199**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:59:33**

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

Audit	User	Time (GMT)
User entered '4 Sep 2020 13:58'	System	04 Sep 2020 20:06:29

US3342199

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:33

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:47:00
User entered '179.0' cm	(b) (4), (b) (6)	04 Sep 2020 20:06:29
DataPoint set to visible.	System	04 Sep 2020 20:02:07

US3342199

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:33

Weight (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:47:00
User entered '87.2' kg	(b) (4), (b) (6)	04 Sep 2020 20:06:29
DataPoint set to visible.	System	04 Sep 2020 20:02:07

**US3342199**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:59:33**

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

Audit	User	Time (GMT)
User entered '27.21513'	System	04 Sep 2020 20:06:29
DataPoint set to visible.	System	04 Sep 2020 20:02:07

**US3342199**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:59:33**

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	04 Sep 2020 20:06:29
DataPoint set to visible.	System	04 Sep 2020 20:02:07

US3342199

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:33

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:47:00
User entered missing code ND - Not Done.	(b) (4), (b) (6)	04 Sep 2020 20:06:29

**US3342199**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:59:33**

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:47:00
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:06:29

US3342199

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:33

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:47:00
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:06:29



US3342199

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:47:00
User entered missing code ND - Not Done.	(b) (4), (b) (6)	04 Sep 2020 20:06:29

**US3342199**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:59:33**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	04 Sep 2020 20:06:29

US3342199

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:33

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:47:00
User entered missing code ND - Not Done.	(b) (4), (b) (6)	04 Sep 2020 20:06:29

US3342199

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	04 Sep 2020 20:06:29

US3342199

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:33

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:47:00
User entered missing code ND - Not Done.	(b) (4), (b) (6)	04 Sep 2020 20:06:29

**US3342199**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:59:33**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	04 Sep 2020 20:06:29

US3342199

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:33

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:47:00
User entered missing code ND - Not Done.	(b) (4), (b) (6)	04 Sep 2020 20:06:29

US3342199

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:33

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	04 Sep 2020 20:06:29



US3342199

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:59:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:01:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 20:06:41

US3342199

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:59:33

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:01:00
User entered '4 Sep 2020'	(b) (4), (b) (6)	04 Sep 2020 20:06:41

US3342199

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:33

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:01:10
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 20:07:21

US3342199

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:33

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:01:10
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 20:07:21

US3342199

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:33

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:01:10
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 20:07:21

US3342199

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:33

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:01:10
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 20:07:21

US3342199

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:33

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:01:10
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 20:07:21

US3342199

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:33

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:01:10
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 20:07:21



US3342199

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:33

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:01:10
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 20:07:21

US3342199

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:33

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:01:10
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 20:07:21

US3342199

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:33

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:01:10
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 20:07:21

US3342199

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:33

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:01:10
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 20:07:21

US3342199

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:33

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:01:10
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 20:07:21

US3342199

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:33

[Other](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:01:10
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 20:07:21

US3342199

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:33

[Specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:01:10
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:07:21

US3342199

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:33

No Risk Identified

Audit	User	Time (GMT)
User closed query 'No Risk Identified' checked and other selections were checked as well. Please review and reconcile.' (Site from System).	System	09 Sep 2020 21:00:57
User entered '0' reason for change: Data Entry Error	John Luna (b) (4)	09 Sep 2020 21:00:57
User opened query 'No Risk Identified' checked and other selections were checked as well. Please review and reconcile.' (Site from System).	System	04 Sep 2020 20:07:21
User entered '1'	(b) (4), (b) (6)	04 Sep 2020 20:07:21



US3342199

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:33

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:01:10
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 20:07:21

US3342199

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:33

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:01:10
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 20:07:21

US3342199

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:33

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:01:10
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 20:07:21

US3342199

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:33

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:01:10
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 20:07:21

US3342199

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:33

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:01:10
User entered 'I'	(b) (4), (b) (6)	04 Sep 2020 20:07:21

US3342199

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:33

[Other](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 20:07:21

US3342199

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:33

[Specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:01:10
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:07:21

**US3342199**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:59:33**

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:29:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 20:07:34



US3342199

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:59:33

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:29:29
User entered '04 Sep 2020' reason for change: Data Entry Error	Eileen Euperio (b) (4)	10 Nov 2020 17:00:07
User entered '4 Sep 2020'	(b) (4)	
	(b) (4), (b) (6)	04 Sep 2020 20:07:34

US3342199

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:59:33

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:29:29
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	04 Sep 2020 20:07:34

**US3342199**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:59:33**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	04 Sep 2020 20:07:34

US3342199

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:59:33

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:29:39
User entered '04 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 19:49:52

US3342199

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:59:33

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:29:39
User entered '111835'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 19:49:52

US3342199

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:59:33

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:29:39
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 19:49:52

US3342199

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:59:33

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:29:39
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 20:07:49

**US3342199**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 26 Nov 2020 10:59:33**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:29:39
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 20:07:49



US3342199

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:59:33

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:29:39
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 20:07:49

US3342199

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:59:33

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:29:39
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 20:07:49

**US3342199**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 26 Nov 2020 10:59:33**

[Liver Disease](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:29:39
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 20:07:49

**US3342199**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 26 Nov 2020 10:59:33**

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

Audit	User	Time (GMT)
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:29:01
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:28:59

US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:59:33

[Height](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:29:57
User entered missing code ND - Not Done.	(b) (4), (b) (6)	04 Sep 2020 20:08:05

US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:59:33

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:29:57
User entered missing code ND - Not Done.	(b) (4), (b) (6)	04 Sep 2020 20:08:05

US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:59:33

[Height](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:29:57
User entered missing code ND - Not Done.	(b) (4), (b) (6)	04 Sep 2020 20:08:05

US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:59:33

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:29:57
User entered missing code ND - Not Done.	(b) (4), (b) (6)	04 Sep 2020 20:08:05



US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:33

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	04 Sep 2020 20:08:05

US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:29:57
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 21:10:22
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Sep 2020 21:10:22
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 21:10:22
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 20:08:05
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:08:05

US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:29:57
User entered '4 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 21:10:22
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:08:05

US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:33

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:29:57
User entered '13:59' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 21:10:22
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:08:05

**US3342199**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:59:33**

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

Audit	User	Time (GMT)
User entered '4 Sep 2020 13:59'	System	04 Sep 2020 21:10:22
User entered empty.	System	04 Sep 2020 20:08:05

US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:33

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:29:57
User entered '98.1' F reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 21:10:22
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:08:05

US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:33

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:29:57
User closed query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 21:10:37
Query 'Data is required. Please provide.' answered by System data change (Site from System).		04 Sep 2020 21:10:37
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 21:10:37
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 21:10:22
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:08:05

US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:33

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:29:57
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:08:05



US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:29:57
User entered '56' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 21:10:22
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:08:05

**US3342199**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:59:33**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	04 Sep 2020 21:10:22
User entered empty.	System	04 Sep 2020 20:08:05

US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:33

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:29:57
User entered '14' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 21:10:22
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:08:05

**US3342199**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:59:33**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	04 Sep 2020 21:10:22
User entered empty.	System	04 Sep 2020 20:08:05

US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:33

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:29:57
User entered '136' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 21:10:22
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:08:05

**US3342199**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:59:33**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	04 Sep 2020 21:10:22
User entered empty.	System	04 Sep 2020 20:08:05

US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:29:57
User entered '86' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 21:10:22
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:08:05

**US3342199**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:59:33**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	04 Sep 2020 21:10:22
User entered empty.	System	04 Sep 2020 20:08:05



US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:59:33

[Height](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:29:57
User entered missing code ND - Not Done.	(b) (4), (b) (6)	04 Sep 2020 20:08:05

US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:59:33

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:29:57
User entered missing code ND - Not Done.	(b) (4), (b) (6)	04 Sep 2020 20:08:05

US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:33

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	04 Sep 2020 20:08:05

US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:29:57
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 21:10:22
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Sep 2020 21:10:22
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 21:10:22
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 20:08:05
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:08:05

US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:29:57
User entered '4 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 21:10:22
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:08:05

US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:33

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:29:57
User entered '16:00' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 21:10:22
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:08:05

**US3342199**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:59:33**

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

Audit	User	Time (GMT)
User entered '4 Sep 2020 16:00'	System	04 Sep 2020 21:10:22
User entered empty.	System	04 Sep 2020 20:08:05

US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:33

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:29:57
User entered '98.1' F reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 21:10:22
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:08:05



US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:33

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:29:57
User closed query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 21:10:52
Query 'Data is required. Please provide.' answered by System data change (Site from System).		04 Sep 2020 21:10:52
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 21:10:52
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 21:10:22
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:08:05

US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:33

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:29:57
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:08:05

US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:29:57
User entered '56' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 21:10:22
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:08:05

**US3342199**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:59:33**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	04 Sep 2020 21:10:22
User entered empty.	System	04 Sep 2020 20:08:05

US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:33

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:29:57
User entered '15' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 21:10:22
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:08:05

**US3342199**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:59:33**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	04 Sep 2020 21:10:22
User entered empty.	System	04 Sep 2020 20:08:05

US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:33

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:29:57
User entered '149' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 21:10:22
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:08:05

**US3342199**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:59:33**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	04 Sep 2020 21:10:22
User entered empty.	System	04 Sep 2020 20:08:05



US3342199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:29:57
User entered '88' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 21:10:22
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:08:05

**US3342199**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:59:33**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	04 Sep 2020 21:10:22
User entered empty.	System	04 Sep 2020 20:08:05

US3342199

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:59:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:30:06
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 20:08:13

US3342199

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:59:33

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:30:06
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:08:13

US3342199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:59:33

[Was study treatment given?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:30:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 20:37:32

US3342199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:59:33

[If No, reason not given](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:30:11
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:37:32

US3342199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:59:33

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:30:11
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:37:32

US3342199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:59:33

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	04 Sep 2020 20:37:32



US3342199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:59:33

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:30:11
User entered '4 Sep 2020'	(b) (4), (b) (6)	04 Sep 2020 20:37:32

US3342199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:59:33

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:30:11
User entered '15:28'	(b) (4), (b) (6)	04 Sep 2020 20:37:32

**US3342199**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:59:33**

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

Audit	User	Time (GMT)
User entered '4 Sep 2020 15:28'	System	04 Sep 2020 20:37:32

US3342199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:59:33

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:30:11
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	04 Sep 2020 20:37:32

US3342199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:59:33

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:30:11
User entered 'ONCE'	System	04 Sep 2020 20:37:32

US3342199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:59:33

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	04 Sep 2020 20:37:32

US3342199

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:59:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:30:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 20:09:19

US3342199

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:59:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:30:18
User entered '4 Sep 2020'	(b) (4), (b) (6)	04 Sep 2020 20:09:19



US3342199

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:59:33

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:30:18
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 20:58:59
User entered '15:02' reason for change: Data Entry Error	Darrell O'Brien (b) (4)	08 Sep 2020 20:58:59
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	04 Sep 2020 20:09:19
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:09:19

**US3342199**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:59:33**

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

Audit	User	Time (GMT)
User entered '4 Sep 2020 15:02'	System	08 Sep 2020 20:58:59
User entered empty.	System	04 Sep 2020 20:09:19

US3342199

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:59:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:30:25
User entered '4 Sep 2020'	(b) (4), (b) (6)	04 Sep 2020 20:09:30

US3342199

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:59:33

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	04 Sep 2020 20:09:30

US3342199

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:59:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:30:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 20:09:30

US3342199

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:59:33

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:30:25
User closed query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	08 Sep 2020 20:58:49
Query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' answered by data change (Site from System).	System	08 Sep 2020 20:58:49
User entered '15:04' reason for change: Data Entry Error	Darrell O'Brien (b) (4)	08 Sep 2020 20:58:49
User opened query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	04 Sep 2020 20:09:30
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:09:30

**US3342199**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 10:59:33**

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

Audit	User	Time (GMT)
User entered '4 Sep 2020 15:04'	System	08 Sep 2020 20:58:49
User entered empty.	System	04 Sep 2020 20:09:30

US3342199

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:59:33

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	04 Sep 2020 20:09:30



US3342199

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:59:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:30:25
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 20:58:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Sep 2020 20:58:49
User entered 'No (N)' reason for change: Data Entry Error	Darrell O'Brien (b) (4)	08 Sep 2020 20:58:49
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 20:09:30
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:09:30

**US3342199**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 10:59:33**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:30:25
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:09:30

**US3342199**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 10:59:33**

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

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 20:09:30

US3342199

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:59:33

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 17:30:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 20:09:38

**US3342199**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:59:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 20:09:38

**US3342199**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:37:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 20:37:32

**US3342199**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:33**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T16:02:17', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '18091cb0-15d0-4e00-8e6f-36d5d264c1cc'	System	04 Sep 2020 21:02:37
User entered 'Yes (Y)'	System	04 Sep 2020 21:02:37

**US3342199**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:33**

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T16:02:22', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '18091cb0-15d0-4e00-8e6f-36d5d264c1cc'	System	04 Sep 2020 21:02:37
User entered '98.1'	System	04 Sep 2020 21:02:37



US3342199

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:59:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T16:02:26', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '18091cb0-15d0-4e00-8e6f-36d5d264c1cc'	System	04 Sep 2020 21:02:37
User entered 'No (N)'	System	04 Sep 2020 21:02:37

**US3342199**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T16:02:31', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '18091cb0-15d0-4e00-8e6f-36d5d264c1cc'	System	04 Sep 2020 21:02:37
User entered '04 Sep 2020 16:02'	System	04 Sep 2020 21:02:37

**US3342199**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 15:48'	System	04 Sep 2020 20:37:32

**US3342199**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 18:18'	System	04 Sep 2020 20:37:32

**US3342199**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:37:32
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:59:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T21:16:28', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '617f20f9-0124-4e58-b7dc-6a5299df5a3d'	System	05 Sep 2020 02:16:53
User entered 'Yes (Y)'	System	05 Sep 2020 02:16:53

**US3342199**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:33**

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T21:16:39', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '617f20f9-0124-4e58-b7dc-6a5299df5a3d'	System	05 Sep 2020 02:16:53
User entered '98.1'	System	05 Sep 2020 02:16:53

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:59:33

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T21:16:42', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '617f20f9-0124-4e58-b7dc-6a5299df5a3d'	System	05 Sep 2020 02:16:53
User entered 'No (N)'	System	05 Sep 2020 02:16:53



**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T21:16:50', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '617f20f9-0124-4e58-b7dc-6a5299df5a3d'	System	05 Sep 2020 02:16:53
User entered '04 Sep 2020 21:16'	System	05 Sep 2020 02:16:53

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 19:13'	System	04 Sep 2020 20:37:32

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 20:37:32

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:37:32
User entered 'Day 2'	System	04 Sep 2020 20:37:32

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:59:33**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-05T22:46:49', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '566e2d68-77d3-4432-ad1a-d0987f644473'	System	06 Sep 2020 03:47:01
User entered 'Yes (Y)'	System	06 Sep 2020 03:47:01

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:59:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-05T22:46:54', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '566e2d68-77d3-4432-ad1a-d0987f644473'	System	06 Sep 2020 03:47:01
User entered '96.8'	System	06 Sep 2020 03:47:01

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:59:33

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-05T22:46:57', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '566e2d68-77d3-4432-ad1a-d0987f644473'	System	06 Sep 2020 03:47:01
User entered 'No (N)'	System	06 Sep 2020 03:47:01

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-05T22:46:59', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '566e2d68-77d3-4432-ad1a-d0987f644473'	System	06 Sep 2020 03:47:01
User entered '05 Sep 2020 22:46'	System	06 Sep 2020 03:47:01



**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 20:37:32

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 20:37:32

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:37:32
User entered 'Day 3'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:59:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-06T12:01:04', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b94aa21b-9a5a-48e5-9066-53ad71f1f2a0'	System	06 Sep 2020 17:02:01
User entered 'Yes (Y)'	System	06 Sep 2020 17:02:01

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:59:33**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-06T12:01:10', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b94aa21b-9a5a-48e5-9066-53ad71f1f2a0'	System	06 Sep 2020 17:02:01
User entered '98.1'	System	06 Sep 2020 17:02:01

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:59:33

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-06T12:01:17', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b94aa21b-9a5a-48e5-9066-53ad71f1f2a0'	System	06 Sep 2020 17:02:01
User entered 'Yes (Y)'	System	06 Sep 2020 17:02:01

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:59:33

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	05 Oct 2020 08:22:52
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'data entered' (Site from System).	Eileen Euperio (b) (4)	02 Oct 2020 18:04:53
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).	System	06 Sep 2020 17:02:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-06T12:01:24', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b94aa21b-9a5a-48e5-9066-53ad71f1f2a0'	System	06 Sep 2020 17:02:01
User entered '1'	System	06 Sep 2020 17:02:01

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:59:33**

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-06T12:01:24', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b94aa21b-9a5a-48e5-9066-53ad71f1f2a0'	System	06 Sep 2020 17:02:01
User entered '0'	System	06 Sep 2020 17:02:01



**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-06T12:01:27', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b94aa21b-9a5a-48e5-9066-53ad71f1f2a0'	System	06 Sep 2020 17:02:01
User entered '06 Sep 2020 12:01'	System	06 Sep 2020 17:02:01

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 20:37:32

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 20:37:32

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:37:32
User entered 'Day 4'	System	04 Sep 2020 20:37:32

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:59:33**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-07T21:23:49', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '02276d77-1b78-44ce-859a-6cbe4f7746f3'	System	08 Sep 2020 02:24:07
User entered 'Yes (Y)'	System	08 Sep 2020 02:24:07

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:59:33**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-07T21:23:57', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '02276d77-1b78-44ce-859a-6cbe4f7746f3'	System	08 Sep 2020 02:24:07
User entered '97.8'	System	08 Sep 2020 02:24:07

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:59:33

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-07T21:24:00', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '02276d77-1b78-44ce-859a-6cbe4f7746f3'	System	08 Sep 2020 02:24:07
User entered 'No (N)'	System	08 Sep 2020 02:24:07

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-07T21:24:05', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '02276d77-1b78-44ce-859a-6cbe4f7746f3'	System	08 Sep 2020 02:24:07
User entered '07 Sep 2020 21:24'	System	08 Sep 2020 02:24:07



**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 20:37:32

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 20:37:32

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:37:32
User entered 'Day 5'	System	04 Sep 2020 20:37:32

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:59:33**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-08T18:25:44', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '82fecb8-d485-46c4-b393-378943551ea3'	System	08 Sep 2020 23:26:01
User entered 'Yes (Y)'	System	08 Sep 2020 23:26:01

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:59:33**

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-08T18:25:52', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '82fecb8-d485-46c4-b393-378943551ea3' User entered '97.8'	System	08 Sep 2020 23:26:01

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:59:33

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-08T18:25:55', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '82fecb8-d485-46c4-b393-378943551ea3'	System	08 Sep 2020 23:26:01
User entered 'No (N)'	System	08 Sep 2020 23:26:01

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-08T18:25:58', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '82fecb8-d485-46c4-b393-378943551ea3'	System	08 Sep 2020 23:26:01
User entered '08 Sep 2020 18:25'	System	08 Sep 2020 23:26:01

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 20:37:32



**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 20:37:32

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:37:32
User entered 'Day 6'	System	04 Sep 2020 20:37:32

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:59:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-09T22:52:49', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '5d26e6f1-e457-44c9-bdc4-8ec1b4f90c17'	System	10 Sep 2020 03:53:04
User entered 'Yes (Y)'	System	10 Sep 2020 03:53:04

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:59:33**

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-09T22:52:56', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '5d26e6f1-e457-44c9-bdc4-8ec1b4f90c17'	System	10 Sep 2020 03:53:04
User entered '97.8'	System	10 Sep 2020 03:53:04

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:59:33

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-09T22:53:00', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '5d26e6f1-e457-44c9-bdc4-8ec1b4f90c17'	System	10 Sep 2020 03:53:04
User entered 'No (N)'	System	10 Sep 2020 03:53:04

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-09T22:53:03', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '5d26e6f1-e457-44c9-bdc4-8ec1b4f90c17'	System	10 Sep 2020 03:53:04
User entered '09 Sep 2020 22:53'	System	10 Sep 2020 03:53:04

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 20:37:32

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 20:37:32



**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:37:32
User entered 'Day 7'	System	04 Sep 2020 20:37:32

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:59:33**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-10T12:06:10', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'e00ac1c2-6c44-4ccf-871f-e1e61db9ee8f'	System	10 Sep 2020 17:06:21
User entered 'Yes (Y)'	System	10 Sep 2020 17:06:21

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:59:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-10T12:06:14', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'e00ac1c2-6c44-4ccf-871f-e1e61db9ee8f' User entered '98.3'	System	10 Sep 2020 17:06:21

US3342199

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:59:33

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-10T12:06:17', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'e00ac1c2-6c44-4ccf-871f-e1e61db9ee8f' User entered 'No (N)'	System	10 Sep 2020 17:06:21

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-10T12:06:19', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'e00ac1c2-6c44-4ccf-871f-e1e61db9ee8f' User entered '10 Sep 2020 12:06'	System	10 Sep 2020 17:06:21
	System	10 Sep 2020 17:06:21

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 20:37:32

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 20:37:32

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:37:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 20:37:32



US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:59:33

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T16:03:01', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'c50c40fa-67ec-414b-ad79-faa8c09e402c'	System	04 Sep 2020 21:03:32
User entered 'None (1)'	System	04 Sep 2020 21:03:32

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:33**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T16:03:12', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'c50c40fa-67ec-414b-ad79-faa8c09e402c'	System	04 Sep 2020 21:03:32
User entered 'No (N)'	System	04 Sep 2020 21:03:32

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:59:33

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T16:03:17', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'c50c40fa-67ec-414b-ad79-faa8c09e402c'	System	04 Sep 2020 21:03:32
User entered 'No (N)'	System	04 Sep 2020 21:03:32

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:59:33

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T16:03:22', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'c50c40fa-67ec-414b-ad79-faa8c09e402c'	System	04 Sep 2020 21:03:32
User entered 'None (1)'	System	04 Sep 2020 21:03:32

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T16:03:27', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'c50c40fa-67ec-414b-ad79-faa8c09e402c'	System	04 Sep 2020 21:03:32
User entered '04 Sep 2020 16:03'	System	04 Sep 2020 21:03:32

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 15:48'	System	04 Sep 2020 20:37:32

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 18:18'	System	04 Sep 2020 20:37:32

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:37:32
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 20:37:32



US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:59:33

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T21:16:58', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '71c99170-2052-4e4d-a52c-c715bfc8142'	System	05 Sep 2020 02:17:40
User entered 'None (1)'	System	05 Sep 2020 02:17:40

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:59:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T21:17:18', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '71c99170-2052-4e4d-a52c-c715bfcb8142'	System	05 Sep 2020 02:17:40
User entered 'No (N)'	System	05 Sep 2020 02:17:40

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:59:33

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T21:17:21', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '71c99170-2052-4e4d-a52c-c715bfcb8142'	System	05 Sep 2020 02:17:40
User entered 'No (N)'	System	05 Sep 2020 02:17:40

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:59:33

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T21:17:31', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '71c99170-2052-4e4d-a52c-c715bfc8142'	System	05 Sep 2020 02:17:40
User entered 'None (1)'	System	05 Sep 2020 02:17:40

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T21:17:38', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '71c99170-2052-4e4d-a52c-c715bfc8142'	System	05 Sep 2020 02:17:40
User entered '04 Sep 2020 21:17'	System	05 Sep 2020 02:17:40

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 19:13'	System	04 Sep 2020 20:37:32

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 20:37:32

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:37:32
User entered 'Day 2'	System	04 Sep 2020 20:37:32



US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:59:33

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-05T22:44:02', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'f4218fc5-1124-4d60-bd25-1f53abfd38d5'	System	06 Sep 2020 03:44:17
User entered 'None (1)'	System	06 Sep 2020 03:44:17

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:59:33**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-05T22:44:06', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'f4218fc5-1124-4d60-bd25-1f53abfd38d5'	System	06 Sep 2020 03:44:17
User entered 'No (N)'	System	06 Sep 2020 03:44:17

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:59:33

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-05T22:44:09', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'f4218fc5-1124-4d60-bd25-1f53abfd38d5'	System	06 Sep 2020 03:44:17
User entered 'No (N)'	System	06 Sep 2020 03:44:17

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:59:33

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-05T22:44:11', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'f4218fc5-1124-4d60-bd25-1f53abfd38d5'	System	06 Sep 2020 03:44:17
User entered 'None (1)'	System	06 Sep 2020 03:44:17

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-05T22:44:15', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'f4218fc5-1124-4d60-bd25-1f53abfd38d5'	System	06 Sep 2020 03:44:17
User entered '05 Sep 2020 22:44'	System	06 Sep 2020 03:44:17

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 20:37:32

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 20:37:32

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:37:32
User entered 'Day 3'	System	04 Sep 2020 20:37:32



US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:59:33

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-06T12:00:13', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'c2ea3adf-c3a1-4668-aee4-cb57c14c348f'	System	06 Sep 2020 17:00:27
User entered 'None (1)'	System	06 Sep 2020 17:00:27

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:59:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-06T12:00:15', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'c2ea3adf-c3a1-4668-aee4-cb57c14c348f'	System	06 Sep 2020 17:00:27
User entered 'No (N)'	System	06 Sep 2020 17:00:27

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:59:33

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-06T12:00:18', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'c2ea3adf-c3a1-4668-aee4-cb57c14c348f'	System	06 Sep 2020 17:00:27
User entered 'No (N)'	System	06 Sep 2020 17:00:27

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:59:33

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-06T12:00:21', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'c2ea3adf-c3a1-4668-aee4-cb57c14c348f' User entered 'None (1)'	System	06 Sep 2020 17:00:27
	System	06 Sep 2020 17:00:27

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-06T12:00:24', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'c2ea3adf-c3a1-4668-aee4-cb57c14c348f' User entered '06 Sep 2020 12:00'	System	06 Sep 2020 17:00:27
	System	06 Sep 2020 17:00:27

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 20:37:32

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 20:37:32

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:37:32
User entered 'Day 4'	System	04 Sep 2020 20:37:32



US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:59:33

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-07T21:24:08', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'c26aee46-4521-4f41-ba67-7cd4f023d10e'	System	08 Sep 2020 02:24:26
User entered 'None (1)'	System	08 Sep 2020 02:24:26

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:59:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-07T21:24:12', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'c26aee46-4521-4f41-ba67-7cd4f023d10e'	System	08 Sep 2020 02:24:26
User entered 'No (N)'	System	08 Sep 2020 02:24:26

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:59:33

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-07T21:24:14', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'c26aee46-4521-4f41-ba67-7cd4f023d10e'	System	08 Sep 2020 02:24:26
User entered 'No (N)'	System	08 Sep 2020 02:24:26

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:59:33

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-07T21:24:17', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'c26aee46-4521-4f41-ba67-7cd4f023d10e'	System	08 Sep 2020 02:24:26
User entered 'None (1)'	System	08 Sep 2020 02:24:26

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-07T21:24:23', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'c26aee46-4521-4f41-ba67-7cd4f023d10e' User entered '07 Sep 2020 21:24'	System	08 Sep 2020 02:24:26
	System	08 Sep 2020 02:24:26

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 20:37:32

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 20:37:32

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:37:32
User entered 'Day 5'	System	04 Sep 2020 20:37:32



US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:59:33

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-08T18:26:01', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '1b1b5f73-bbb9-4b19-a8a8-b46b255fb3b3'	System	08 Sep 2020 23:26:16
User entered 'None (1)'	System	08 Sep 2020 23:26:16

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:59:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-08T18:26:04', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '1b1b5f73-bbb9-4b19-a8a8-b46b255fb3b3'	System	08 Sep 2020 23:26:16
User entered 'No (N)'	System	08 Sep 2020 23:26:16

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:59:33

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-08T18:26:06', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '1b1b5f73-bbb9-4b19-a8a8-b46b255fb3b3'	System	08 Sep 2020 23:26:16
User entered 'No (N)'	System	08 Sep 2020 23:26:16

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:59:33

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-08T18:26:08', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '1b1b5f73-bbb9-4b19-a8a8-b46b255fb3b3'	System	08 Sep 2020 23:26:16
User entered 'None (1)'	System	08 Sep 2020 23:26:16

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-08T18:26:10', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '1b1b5f73-bbb9-4b19-a8a8-b46b255fb3b3'	System	08 Sep 2020 23:26:16
User entered '08 Sep 2020 18:26'	System	08 Sep 2020 23:26:16

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 20:37:32

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 20:37:32

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:37:32
User entered 'Day 6'	System	04 Sep 2020 20:37:32



US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:59:33

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-09T22:53:06', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b191f6e4-74b0-44b9-870f-c1590b55531a'	System	10 Sep 2020 03:53:17
User entered 'None (1)'	System	10 Sep 2020 03:53:17

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:59:33**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-09T22:53:09', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b191f6e4-74b0-44b9-870f-c1590b55531a'	System	10 Sep 2020 03:53:17
User entered 'No (N)'	System	10 Sep 2020 03:53:17

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:59:33

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-09T22:53:11', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b191f6e4-74b0-44b9-870f-c1590b55531a'	System	10 Sep 2020 03:53:17
User entered 'No (N)'	System	10 Sep 2020 03:53:17

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:59:33

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-09T22:53:13', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b191f6e4-74b0-44b9-870f-c1590b55531a' User entered 'None (1)'	System	10 Sep 2020 03:53:17
	System	10 Sep 2020 03:53:17

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-09T22:53:15', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b191f6e4-74b0-44b9-870f-c1590b55531a' User entered '09 Sep 2020 22:53'	System	10 Sep 2020 03:53:17
	System	10 Sep 2020 03:53:17

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 20:37:32

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 20:37:32

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:37:32
User entered 'Day 7'	System	04 Sep 2020 20:37:32



US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:59:33

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-10T12:06:22', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '06dc0581-2c8e-4a04-b3da-f0ee32e42fbb'	System	10 Sep 2020 17:06:32
User entered 'None (1)'	System	10 Sep 2020 17:06:32

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:59:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-10T12:06:24', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '06dc0581-2c8e-4a04-b3da-f0ee32e42fbb'	System	10 Sep 2020 17:06:32
User entered 'No (N)'	System	10 Sep 2020 17:06:32

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:59:33

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-10T12:06:26', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '06dc0581-2c8e-4a04-b3da-f0ee32e42fbb'	System	10 Sep 2020 17:06:32
User entered 'No (N)'	System	10 Sep 2020 17:06:32

US3342199

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:59:33

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-10T12:06:27', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '06dc0581-2c8e-4a04-b3da-f0ee32e42fbb'	System	10 Sep 2020 17:06:32
User entered 'None (1)'	System	10 Sep 2020 17:06:32

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-10T12:06:30', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '06dc0581-2c8e-4a04-b3da-f0ee32e42fbb'	System	10 Sep 2020 17:06:32
User entered '10 Sep 2020 12:06'	System	10 Sep 2020 17:06:32

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 20:37:32

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 20:37:32

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:37:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 20:37:32



**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:33**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T16:03:33', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'c4e94ec9-eb55-492d-85ca-7a48a3a05ef4'	System	04 Sep 2020 21:04:01
User entered 'None (0)'	System	04 Sep 2020 21:04:01

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:33**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T16:03:36', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'c4e94ec9-eb55-492d-85ca-7a48a3a05ef4'	System	04 Sep 2020 21:04:01
User entered 'None (0)'	System	04 Sep 2020 21:04:01

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:33**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T16:03:38', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'c4e94ec9-eb55-492d-85ca-7a48a3a05ef4'	System	04 Sep 2020 21:04:01
User entered 'None (0)'	System	04 Sep 2020 21:04:01

US3342199

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:59:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T16:03:41', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'c4e94ec9-eb55-492d-85ca-7a48a3a05ef4'	System	04 Sep 2020 21:04:01
User entered 'None (0)'	System	04 Sep 2020 21:04:01

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:33**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T16:03:43', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'c4e94ec9-eb55-492d-85ca-7a48a3a05ef4'	System	04 Sep 2020 21:04:01
User entered 'None (0)'	System	04 Sep 2020 21:04:01

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:33**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T16:03:48', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'c4e94ec9-eb55-492d-85ca-7a48a3a05ef4'	System	04 Sep 2020 21:04:01
User entered 'None (0)'	System	04 Sep 2020 21:04:01

US3342199

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:59:33

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T16:03:54', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'c4e94ec9-eb55-492d-85ca-7a48a3a05ef4'	System	04 Sep 2020 21:04:01
User entered 'No (N)'	System	04 Sep 2020 21:04:01

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T16:03:58', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'c4e94ec9-eb55-492d-85ca-7a48a3a05ef4' User entered '04 Sep 2020 16:03'	System	04 Sep 2020 21:04:01
	System	04 Sep 2020 21:04:01



**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 15:48'	System	04 Sep 2020 20:37:32

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 18:18'	System	04 Sep 2020 20:37:32

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:37:32
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 20:37:32

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:33**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T21:17:44', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'a6300e5b-987e-447a-b718-d2fe26a3921b'	System	05 Sep 2020 02:18:08
User entered 'None (0)'	System	05 Sep 2020 02:18:08

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:33**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T21:17:50', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'a6300e5b-987e-447a-b718-d2fe26a3921b' User entered 'None (0)'	System	05 Sep 2020 02:18:08
	System	05 Sep 2020 02:18:08

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:33**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T21:17:53', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'a6300e5b-987e-447a-b718-d2fe26a3921b'	System	05 Sep 2020 02:18:08
User entered 'None (0)'	System	05 Sep 2020 02:18:08

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:33**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T21:17:55', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'a6300e5b-987e-447a-b718-d2fe26a3921b'	System	05 Sep 2020 02:18:08
User entered 'None (0)'	System	05 Sep 2020 02:18:08

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:33**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T21:17:57', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'a6300e5b-987e-447a-b718-d2fe26a3921b'	System	05 Sep 2020 02:18:08
User entered 'None (0)'	System	05 Sep 2020 02:18:08



**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:33**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T21:17:58', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'a6300e5b-987e-447a-b718-d2fe26a3921b'	System	05 Sep 2020 02:18:08
User entered 'None (0)'	System	05 Sep 2020 02:18:08

US3342199

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:59:33

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T21:18:02', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'a6300e5b-987e-447a-b718-d2fe26a3921b'	System	05 Sep 2020 02:18:08
User entered 'No (N)'	System	05 Sep 2020 02:18:08

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-04T21:18:05', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'a6300e5b-987e-447a-b718-d2fe26a3921b' User entered '04 Sep 2020 21:18'	System	05 Sep 2020 02:18:08
	System	05 Sep 2020 02:18:08

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 19:13'	System	04 Sep 2020 20:37:32

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 20:37:32

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:37:32
User entered 'Day 2'	System	04 Sep 2020 20:37:32

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:59:33**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-05T22:44:18', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '7d0248a3-6af1-4122-a6e2-887be401a602'	System	06 Sep 2020 03:44:37
User entered 'None (0)'	System	06 Sep 2020 03:44:37

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:59:33**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-05T22:44:21', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '7d0248a3-6af1-4122-a6e2-887be401a602'	System	06 Sep 2020 03:44:37
User entered 'None (0)'	System	06 Sep 2020 03:44:37



**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:59:33**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-05T22:44:23', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '7d0248a3-6af1-4122-a6e2-887be401a602'	System	06 Sep 2020 03:44:37
User entered 'None (0)'	System	06 Sep 2020 03:44:37

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:59:33**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-05T22:44:25', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '7d0248a3-6af1-4122-a6e2-887be401a602'	System	06 Sep 2020 03:44:37
User entered 'None (0)'	System	06 Sep 2020 03:44:37

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:59:33**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-05T22:44:27', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '7d0248a3-6af1-4122-a6e2-887be401a602'	System	06 Sep 2020 03:44:37
User entered 'None (0)'	System	06 Sep 2020 03:44:37

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:59:33**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-05T22:44:28', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '7d0248a3-6af1-4122-a6e2-887be401a602'	System	06 Sep 2020 03:44:37
User entered 'None (0)'	System	06 Sep 2020 03:44:37

US3342199

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:59:33

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-05T22:44:31', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '7d0248a3-6af1-4122-a6e2-887be401a602'	System	06 Sep 2020 03:44:37
User entered 'No (N)'	System	06 Sep 2020 03:44:37

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-05T22:44:33', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '7d0248a3-6af1-4122-a6e2-887be401a602'	System	06 Sep 2020 03:44:37
User entered '05 Sep 2020 22:44'	System	06 Sep 2020 03:44:37

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 20:37:32

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 20:37:32



**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:37:32
User entered 'Day 3'	System	04 Sep 2020 20:37:32

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:59:33**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-06T12:00:29', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '15913778-4e90-4948-805f-946f6142fbc8'	System	06 Sep 2020 17:01:17
User entered 'None (0)'	System	06 Sep 2020 17:01:17

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:59:33**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-06T12:00:34', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '15913778-4e90-4948-805f-946f6142fbc8'	System	06 Sep 2020 17:01:17
User entered 'None (0)'	System	06 Sep 2020 17:01:17

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:59:33**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-06T12:00:43', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '15913778-4e90-4948-805f-946f6142fbc8'	System	06 Sep 2020 17:01:17
User entered 'None (0)'	System	06 Sep 2020 17:01:17

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:59:33**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-06T12:00:47', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '15913778-4e90-4948-805f-946f6142fbc8'	System	06 Sep 2020 17:01:17
User entered 'None (0)'	System	06 Sep 2020 17:01:17

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:59:33**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-06T12:00:49', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '15913778-4e90-4948-805f-946f6142fbc8'	System	06 Sep 2020 17:01:17
User entered 'None (0)'	System	06 Sep 2020 17:01:17

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:59:33**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-06T12:00:51', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '15913778-4e90-4948-805f-946f6142fbc8'	System	06 Sep 2020 17:01:17
User entered 'None (0)'	System	06 Sep 2020 17:01:17

US3342199

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:59:33

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-06T12:00:55', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '15913778-4e90-4948-805f-946f6142fbc8'	System	06 Sep 2020 17:01:17
User entered 'No (N)'	System	06 Sep 2020 17:01:17



**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-06T12:00:57', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '15913778-4e90-4948-805f-946f6142fbc8'	System	06 Sep 2020 17:01:17
User entered '06 Sep 2020 12:00'	System	06 Sep 2020 17:01:17

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 20:37:32

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 20:37:32

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:37:32
User entered 'Day 4'	System	04 Sep 2020 20:37:32

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:59:33**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-07T21:24:27', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '0c38220e-f139-45bb-b4c6-167579f659a7'	System	08 Sep 2020 02:24:51
User entered 'None (0)'	System	08 Sep 2020 02:24:51

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:59:33**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-07T21:24:32', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '0c38220e-f139-45bb-b4c6-167579f659a7'	System	08 Sep 2020 02:24:51
User entered 'None (0)'	System	08 Sep 2020 02:24:51

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:59:33**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-07T21:24:33', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '0c38220e-f139-45bb-b4c6-167579f659a7'	System	08 Sep 2020 02:24:51
User entered 'None (0)'	System	08 Sep 2020 02:24:51

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:59:33**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-07T21:24:35', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '0c38220e-f139-45bb-b4c6-167579f659a7'	System	08 Sep 2020 02:24:51
User entered 'None (0)'	System	08 Sep 2020 02:24:51



**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:59:33**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-07T21:24:39', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '0c38220e-f139-45bb-b4c6-167579f659a7'	System	08 Sep 2020 02:24:51
User entered 'None (0)'	System	08 Sep 2020 02:24:51

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:59:33**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-07T21:24:41', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '0c38220e-f139-45bb-b4c6-167579f659a7'	System	08 Sep 2020 02:24:51
User entered 'None (0)'	System	08 Sep 2020 02:24:51

US3342199

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:59:33

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-07T21:24:43', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '0c38220e-f139-45bb-b4c6-167579f659a7'	System	08 Sep 2020 02:24:51
User entered 'No (N)'	System	08 Sep 2020 02:24:51

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-07T21:24:46', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '0c38220e-f139-45bb-b4c6-167579f659a7'	System	08 Sep 2020 02:24:51
User entered '07 Sep 2020 21:24'	System	08 Sep 2020 02:24:51

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 20:37:32

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 20:37:32

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:37:32
User entered 'Day 5'	System	04 Sep 2020 20:37:32

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:59:33**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-08T18:26:14', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'e3f4f74e-70b4-4fda-9024-a494c745b0f5'	System	08 Sep 2020 23:26:39
User entered 'None (0)'	System	08 Sep 2020 23:26:39



**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:59:33**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-08T18:26:21', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'e3f4f74e-70b4-4fda-9024-a494c745b0f5'	System	08 Sep 2020 23:26:39
User entered 'None (0)'	System	08 Sep 2020 23:26:39

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:59:33**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-08T18:26:23', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'e3f4f74e-70b4-4fda-9024-a494c745b0f5'	System	08 Sep 2020 23:26:39
User entered 'None (0)'	System	08 Sep 2020 23:26:39

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:59:33**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-08T18:26:24', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'e3f4f74e-70b4-4fda-9024-a494c745b0f5'	System	08 Sep 2020 23:26:39
User entered 'None (0)'	System	08 Sep 2020 23:26:39

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:59:33**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-08T18:26:27', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'e3f4f74e-70b4-4fda-9024-a494c745b0f5'	System	08 Sep 2020 23:26:39
User entered 'None (0)'	System	08 Sep 2020 23:26:39

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:59:33**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-08T18:26:29', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'e3f4f74e-70b4-4fda-9024-a494c745b0f5'	System	08 Sep 2020 23:26:39
User entered 'None (0)'	System	08 Sep 2020 23:26:39

US3342199

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:59:33

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-08T18:26:35', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'e3f4f74e-70b4-4fda-9024-a494c745b0f5'	System	08 Sep 2020 23:26:39
User entered 'No (N)'	System	08 Sep 2020 23:26:39

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-08T18:26:38', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'e3f4f74e-70b4-4fda-9024-a494c745b0f5'	System	08 Sep 2020 23:26:39
User entered '08 Sep 2020 18:26'	System	08 Sep 2020 23:26:39

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 20:37:32



**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 20:37:32

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:37:32
User entered 'Day 6'	System	04 Sep 2020 20:37:32

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:59:33**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-09T22:53:19', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'eeaa30a0-f239-4a01-b3b1-5af4bae6cab4' User entered 'None (0)'	System	10 Sep 2020 03:53:37

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:59:33**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-09T22:53:21', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'eeaa30a0-f239-4a01-b3b1-5af4bae6cab4' User entered 'None (0)'	System	10 Sep 2020 03:53:37

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:59:33**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-09T22:53:23', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'eeaa30a0-f239-4a01-b3b1-5af4bae6cab4' User entered 'None (0)'	System	10 Sep 2020 03:53:37

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:59:33**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-09T22:53:25', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'eeaa30a0-f239-4a01-b3b1-5af4bae6cab4'	System	10 Sep 2020 03:53:37
User entered 'None (0)'	System	10 Sep 2020 03:53:37

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:59:33**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-09T22:53:27', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'eeaa30a0-f239-4a01-b3b1-5af4bae6cab4'	System	10 Sep 2020 03:53:37
User entered 'None (0)'	System	10 Sep 2020 03:53:37

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:59:33**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-09T22:53:29', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'eeaa30a0-f239-4a01-b3b1-5af4bae6cab4' User entered 'None (0)'	System	10 Sep 2020 03:53:37



US3342199

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:59:33

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-09T22:53:31', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'eeaa30a0-f239-4a01-b3b1-5af4bae6cab4'	System	10 Sep 2020 03:53:37
User entered 'No (N)'	System	10 Sep 2020 03:53:37

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-09T22:53:33', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'eeaa30a0-f239-4a01-b3b1-5af4bae6cab4' User entered '09 Sep 2020 22:53'	System	10 Sep 2020 03:53:37

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 20:37:32

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 20:37:32

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:37:32
User entered 'Day 7'	System	04 Sep 2020 20:37:32

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:59:33**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-10T12:06:36', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '4b9591b3-9fa6-42c7-bc48-b904fb067e90'	System	10 Sep 2020 17:06:57
User entered 'No interference with activity (1)'	System	10 Sep 2020 17:06:57

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:59:33**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-10T12:06:38', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '4b9591b3-9fa6-42c7-bc48-b904fb067e90'	System	10 Sep 2020 17:06:57
User entered 'None (0)'	System	10 Sep 2020 17:06:57

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:59:33**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-10T12:06:40', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '4b9591b3-9fa6-42c7-bc48-b904fb067e90'	System	10 Sep 2020 17:06:57
User entered 'None (0)'	System	10 Sep 2020 17:06:57



**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:59:33**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-10T12:06:42', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '4b9591b3-9fa6-42c7-bc48-b904fb067e90'	System	10 Sep 2020 17:06:57
User entered 'None (0)'	System	10 Sep 2020 17:06:57

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:59:33**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-10T12:06:43', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '4b9591b3-9fa6-42c7-bc48-b904fb067e90'	System	10 Sep 2020 17:06:57
User entered 'None (0)'	System	10 Sep 2020 17:06:57

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:59:33**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-10T12:06:48', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '4b9591b3-9fa6-42c7-bc48-b904fb067e90'	System	10 Sep 2020 17:06:57
User entered 'None (0)'	System	10 Sep 2020 17:06:57

US3342199

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:59:33

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-10T12:06:51', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '4b9591b3-9fa6-42c7-bc48-b904fb067e90'	System	10 Sep 2020 17:06:57
User entered 'No (N)'	System	10 Sep 2020 17:06:57

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-10T12:06:54', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '4b9591b3-9fa6-42c7-bc48-b904fb067e90'	System	10 Sep 2020 17:06:57
User entered '10 Sep 2020 12:06'	System	10 Sep 2020 17:06:57

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 20:37:32

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 20:37:32

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(8)**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 17:06:57
User entered 'Day 8'	System	10 Sep 2020 17:06:57



**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(8)**

**Generated On: 26 Nov 2020 10:59:33**

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-11T13:33:54', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '3249b83c-917e-4fb7-88e8-c4a976e543bc' User entered 'None (0)'	System	11 Sep 2020 18:33:59

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(8)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-11T13:33:57', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '3249b83c-917e-4fb7-88e8-c4a976e543bc' User entered '11 Sep 2020 13:33'	System	11 Sep 2020 18:33:59
	System	11 Sep 2020 18:33:59

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(8)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 17:06:57

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(8)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 17:06:57

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 17:06:57
User entered 'Day 8'	System	10 Sep 2020 17:06:57

US3342199

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 26 Nov 2020 10:59:33

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-11T13:34:00', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'aad25c6a-e91c-4eaa-b633-b0a60bb841e0'	System	11 Sep 2020 18:34:04
User entered 'No (N)'	System	11 Sep 2020 18:34:04

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-09-11T13:34:03', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'aad25c6a-e91c-4eaa-b633-b0a60bb841e0'	System	11 Sep 2020 18:34:04
User entered '11 Sep 2020 13:34'	System	11 Sep 2020 18:34:04

**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 17:06:57



**US3342199**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 17:06:57

US3342199

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	11 Sep 2020 18:45:42

US3342199

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:33

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	Ethan Shotton (b) (4) (b) (4)	11 Sep 2020 18:45:42

US3342199

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4) (b) (4)	11 Sep 2020 18:45:42

**US3342199**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:59:33**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	Ethan Shotton (b) (4) (b) (4)	11 Sep 2020 18:45:42

US3342199

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	11 Sep 2020 18:45:47

**US3342199**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:59:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Sep 2020 18:45:47

**US3342199**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:59:33**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 18:29:03



US3342199

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:33

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '18 Sep 2020'	(b) (4), (b) (6)	18 Sep 2020 18:29:03

**US3342199**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:59:33**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	18 Sep 2020 18:29:03

**US3342199**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:59:33**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 18:29:03

US3342199

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 18:29:07

**US3342199**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:59:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	18 Sep 2020 18:29:07

**US3342199**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:59:33**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	30 Sep 2020 13:23:33

**US3342199**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:59:33**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Sep 2020'	Eileen Euperio (b) (4) (b) (4)	30 Sep 2020 13:23:33

**US3342199**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:59:33**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Eileen Euperio (b) (4) (b) (4)	30 Sep 2020 13:23:33



**US3342199**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:59:33**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	30 Sep 2020 13:23:33

US3342199

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	30 Sep 2020 13:23:39

**US3342199**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:59:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Sep 2020 13:23:39

US3342199

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:59:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	01 Oct 2020 20:52:30

US3342199

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:59:33

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '1 Oct 2020'	Morgan Schulle (b) (4) (b) (4)	01 Oct 2020 20:52:30

US3342199

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:59:33

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Morgan Schulle (b) (4) (b) (4)	01 Oct 2020 20:52:30

**US3342199**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:59:33**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	01 Oct 2020 20:52:30

US3342199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:33

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	01 Oct 2020 21:40:05



US3342199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:24:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 21:40:05

US3342199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:24:37
User entered '1 Oct 2020'	(b) (4), (b) (6)	01 Oct 2020 21:40:05

**US3342199**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:59:33**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:24:37
User entered '15:19'	(b) (4), (b) (6)	01 Oct 2020 21:40:05

**US3342199**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:59:33**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '1 Oct 2020 15:19'	System	01 Oct 2020 21:40:05

US3342199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:33

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:24:37
User entered '98.8' F	(b) (4), (b) (6)	01 Oct 2020 21:40:05

US3342199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:33

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:24:37
User entered 'Oral (Oral)'	(b) (4), (b) (6)	01 Oct 2020 21:40:05

**US3342199**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:59:33**

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:24:37
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 21:40:05

US3342199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:24:37
User entered '64'	(b) (4), (b) (6)	01 Oct 2020 21:40:05



**US3342199**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:59:33**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	01 Oct 2020 21:40:05

US3342199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:24:37
User entered '14'	(b) (4), (b) (6)	01 Oct 2020 21:40:05

US3342199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	01 Oct 2020 21:40:05

US3342199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:24:37
User entered '133'	(b) (4), (b) (6)	01 Oct 2020 21:40:05

**US3342199**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:59:33**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Oct 2020 21:40:05

US3342199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:33

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:24:37
User entered '76'	(b) (4), (b) (6)	01 Oct 2020 21:40:05

**US3342199**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:59:33**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Oct 2020 21:40:05

**US3342199**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:59:33**

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	01 Oct 2020 21:40:05



US3342199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:24:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 21:40:05

US3342199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:24:37
User entered '1 Oct 2020'	(b) (4), (b) (6)	01 Oct 2020 21:40:05

US3342199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:33

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:24:37
User entered '16:36'	(b) (4), (b) (6)	01 Oct 2020 21:40:05

**US3342199**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:59:33**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '1 Oct 2020 16:36'	System	01 Oct 2020 21:40:05

US3342199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:33

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:24:37
User entered '98.0' F	(b) (4), (b) (6)	01 Oct 2020 21:40:05

US3342199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:33

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:24:37
User entered 'Oral (Oral)'	(b) (4), (b) (6)	01 Oct 2020 21:40:05

US3342199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:33

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:24:37
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 21:40:05

US3342199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:24:37
User entered '59'	(b) (4), (b) (6)	01 Oct 2020 21:40:05



**US3342199**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:59:33**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	01 Oct 2020 21:40:05

US3342199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:24:37
User entered '12'	(b) (4), (b) (6)	01 Oct 2020 21:40:05

US3342199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	01 Oct 2020 21:40:05

US3342199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:33

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:24:37
User entered '114'	(b) (4), (b) (6)	01 Oct 2020 21:40:05

**US3342199**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:59:33**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Oct 2020 21:40:05

US3342199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:33

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:24:37
User entered '68'	(b) (4), (b) (6)	01 Oct 2020 21:40:05

US3342199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:33

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Oct 2020 21:40:05

US3342199

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:59:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:24:52
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	01 Oct 2020 20:52:57



US3342199

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:59:33

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:24:52
User entered '1 Oct 2020'	Morgan Schulle (b) (4) (b) (4)	01 Oct 2020 20:52:57

US3342199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:59:33

[Was study treatment given?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:24:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 21:26:26

US3342199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:59:33

[If No, reason not given](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:24:59
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 21:26:26

US3342199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:59:33

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:24:59
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 21:26:26

**US3342199**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:59:33**

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	01 Oct 2020 21:26:26

US3342199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:59:33

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:24:59
User entered '1 Oct 2020'	(b) (4), (b) (6)	01 Oct 2020 21:26:26

US3342199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:59:33

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:24:59
User entered '16:04'	(b) (4), (b) (6)	01 Oct 2020 21:26:26

**US3342199**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:59:33**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '1 Oct 2020 16:04'	System	01 Oct 2020 21:26:26



US3342199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:59:33

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:24:59
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	01 Oct 2020 21:26:26

US3342199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:59:33

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:24:59
User entered 'ONCE'	System	01 Oct 2020 21:26:26

**US3342199**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:59:33**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	01 Oct 2020 21:26:26

US3342199

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:59:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:25:04
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	06 Oct 2020 13:37:06

US3342199

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:59:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:25:04
User entered '1 Oct 2020'	Morgan Schulle (b) (4) (b) (4)	06 Oct 2020 13:37:06

US3342199

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:59:33

Collection time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:25:04
User entered '15:51'	Morgan Schulle (b) (4) (b) (4)	06 Oct 2020 13:37:06

**US3342199**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:59:33**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '1 Oct 2020 15:51'	System	06 Oct 2020 13:37:06

US3342199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:59:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:25:09
User entered '1 Oct 2020'	Morgan Schulle (b) (4) (b) (4)	06 Oct 2020 13:37:56



US3342199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:59:33

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Morgan Schulle (b) (4) (b) (4)	06 Oct 2020 13:37:56

US3342199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:59:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:25:09
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	06 Oct 2020 13:37:56

**US3342199**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 10:59:33**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:25:09
User entered '15:53'	Morgan Schulle (b) (4) (b) (4)	06 Oct 2020 13:37:56

**US3342199**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 10:59:33**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '1 Oct 2020 15:53'	System	06 Oct 2020 13:37:56

US3342199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:59:33

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Morgan Schulle (b) (4)	06 Oct 2020 13:37:56

US3342199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:59:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:25:09
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	06 Oct 2020 13:37:56

**US3342199**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 10:59:33**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:25:09
User entered empty.	Morgan Schulle (b) (4) (b) (4)	06 Oct 2020 13:37:56

**US3342199**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 10:59:33**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 13:37:56



US3342199

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:25:15
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	01 Oct 2020 20:53:02

**US3342199**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:59:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Oct 2020 20:53:02

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 21:26:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:59:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T16:38:57', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '70f32907-f5cf-480b-a7a6-b23fdcf2ac7c'	System	01 Oct 2020 21:39:18
User entered 'Yes (Y)'	System	01 Oct 2020 21:39:18

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:59:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T16:39:04', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '70f32907-f5cf-480b-a7a6-b23fdcf2ac7c'	System	01 Oct 2020 21:39:18
User entered '98.0'	System	01 Oct 2020 21:39:18

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:59:33

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T16:39:11', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '70f32907-f5cf-480b-a7a6-b23fdcf2ac7c'	System	01 Oct 2020 21:39:18
User entered 'No (N)'	System	01 Oct 2020 21:39:18

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T16:39:13', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '70f32907-f5cf-480b-a7a6-b23fdcf2ac7c'	System	01 Oct 2020 21:39:18
User entered '01 Oct 2020 16:39'	System	01 Oct 2020 21:39:18

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 16:24'	System	01 Oct 2020 21:26:26



US3342199

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:59:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 18:54'	System	01 Oct 2020 21:26:26

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 21:26:26
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 21:26:26

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:33**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T20:42:24', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'd0eae1ff-04c7-4bd5-9657-c86cbb9fe6d5'	System	02 Oct 2020 01:42:37
User entered 'Yes (Y)'	System	02 Oct 2020 01:42:37

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:59:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T20:42:29', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'd0eae1ff-04c7-4bd5-9657-c86cbb9fe6d5'	System	02 Oct 2020 01:42:37
User entered '98.2'	System	02 Oct 2020 01:42:37

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:59:33

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T20:42:32', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'd0eae1ff-04c7-4bd5-9657-c86cbb9fe6d5'	System	02 Oct 2020 01:42:37
User entered 'No (N)'	System	02 Oct 2020 01:42:37

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T20:42:34', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'd0eae1ff-04c7-4bd5-9657-c86cbb9fe6d5'	System	02 Oct 2020 01:42:37
User entered '01 Oct 2020 20:42'	System	02 Oct 2020 01:42:37

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 19:49'	System	01 Oct 2020 21:26:26

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 21:26:26



**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 21:26:26
User entered 'Day 2'	System	01 Oct 2020 21:26:26

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:59:33**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-02T12:00:31', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b5754567-b912-477c-ab98-de4d96322224'	System	02 Oct 2020 17:00:54
User entered 'Yes (Y)'	System	02 Oct 2020 17:00:54

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:59:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-02T12:00:37', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b5754567-b912-477c-ab98-de4d96322224'	System	02 Oct 2020 17:00:54
User entered '97.1'	System	02 Oct 2020 17:00:54

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:59:33

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-02T12:00:39', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b5754567-b912-477c-ab98-de4d96322224'	System	02 Oct 2020 17:00:54
User entered 'No (N)'	System	02 Oct 2020 17:00:54

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-02T12:00:42', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b5754567-b912-477c-ab98-de4d96322224'	System	02 Oct 2020 17:00:54
User entered '02 Oct 2020 12:00'	System	02 Oct 2020 17:00:54

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 21:26:26

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 21:26:26

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 21:26:26
User entered 'Day 3'	System	01 Oct 2020 21:26:26



**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:59:33**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-03T12:10:30', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '506812a7-21b5-48db-8fbf-d1c16c47a1c3'	System	03 Oct 2020 17:10:51
User entered 'Yes (Y)'	System	03 Oct 2020 17:10:51

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:59:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-03T12:10:35', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '506812a7-21b5-48db-8fbf-d1c16c47a1c3'	System	03 Oct 2020 17:10:51
User entered '98.7'	System	03 Oct 2020 17:10:51

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:59:33

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-03T12:10:46', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '506812a7-21b5-48db-8fbf-d1c16c47a1c3'	System	03 Oct 2020 17:10:51
User entered 'No (N)'	System	03 Oct 2020 17:10:51

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-03T12:10:49', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '506812a7-21b5-48db-8fbf-d1c16c47a1c3'	System	03 Oct 2020 17:10:51
User entered '03 Oct 2020 12:10'	System	03 Oct 2020 17:10:51

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:59:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 21:26:26

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 21:26:26

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 21:26:26
User entered 'Day 4'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:59:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-04T20:38:19', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '09d60ece-352d-4a32-a4ca-252710af9282'	System	05 Oct 2020 01:38:33
User entered 'Yes (Y)'	System	05 Oct 2020 01:38:33



US3342199

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:59:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-04T20:38:24', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '09d60ece-352d-4a32-a4ca-252710af9282' User entered '98.1'	System	05 Oct 2020 01:38:33
	System	05 Oct 2020 01:38:33

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:59:33

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-04T20:38:26', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '09d60ece-352d-4a32-a4ca-252710af9282'	System	05 Oct 2020 01:38:33
User entered 'No (N)'	System	05 Oct 2020 01:38:33

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-04T20:38:28', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '09d60ece-352d-4a32-a4ca-252710af9282'	System	05 Oct 2020 01:38:33
User entered '04 Oct 2020 20:38'	System	05 Oct 2020 01:38:33

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:59:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 21:26:26

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 21:26:26

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 21:26:26
User entered 'Day 5'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:59:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-05T13:18:33', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'a333d848-66ef-4ed1-b09d-e5466f07bebb' User entered 'Yes (Y)'	System	05 Oct 2020 18:18:46
	System	05 Oct 2020 18:18:46

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:59:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-05T13:18:38', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'a333d848-66ef-4ed1-b09d-e5466f07bebb' User entered '97.8'	System	05 Oct 2020 18:18:46
	System	05 Oct 2020 18:18:46



US3342199

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:59:33

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-05T13:18:40', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'a333d848-66ef-4ed1-b09d-e5466f07bebb'	System	05 Oct 2020 18:18:46
User entered 'No (N)'	System	05 Oct 2020 18:18:46

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-05T13:18:42', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'a333d848-66ef-4ed1-b09d-e5466f07bebb' User entered '05 Oct 2020 13:18'	System	05 Oct 2020 18:18:46
	System	05 Oct 2020 18:18:46

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 21:26:26

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 21:26:26

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 21:26:26
User entered 'Day 6'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:59:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-06T20:31:44', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'eeae5fd9-5010-468d-9038-cc14e4b4a043'	System	07 Oct 2020 01:33:23
User entered 'Yes (Y)'	System	07 Oct 2020 01:33:23

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:59:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-06T20:33:14', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'eeae5fd9-5010-468d-9038-cc14e4b4a043'	System	07 Oct 2020 01:33:23
User entered '97.7'	System	07 Oct 2020 01:33:23

US3342199

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:59:33

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-06T20:33:17', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'eeae5fd9-5010-468d-9038-cc14e4b4a043'	System	07 Oct 2020 01:33:23
User entered 'No (N)'	System	07 Oct 2020 01:33:23



**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-06T20:33:19', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'eeae5fd9-5010-468d-9038-cc14e4b4a043' User entered '06 Oct 2020 20:33'	System	07 Oct 2020 01:33:23

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 21:26:26

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 21:26:26

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 21:26:26
User entered 'Day 7'	System	01 Oct 2020 21:26:26

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 21:26:26

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 21:26:26

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 21:26:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:59:33

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T16:39:36', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'd49ce8b2-0167-428b-9215-d854fec25775'	System	01 Oct 2020 21:39:50
User entered 'None (1)'	System	01 Oct 2020 21:39:50



US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:59:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T16:39:39', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'd49ce8b2-0167-428b-9215-d854fec25775'	System	01 Oct 2020 21:39:50
User entered 'No (N)'	System	01 Oct 2020 21:39:50

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:59:33

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T16:39:41', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'd49ce8b2-0167-428b-9215-d854fec25775'	System	01 Oct 2020 21:39:50
User entered 'No (N)'	System	01 Oct 2020 21:39:50

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:59:33

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T16:39:45', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'd49ce8b2-0167-428b-9215-d854fec25775'	System	01 Oct 2020 21:39:50
User entered 'None (1)'	System	01 Oct 2020 21:39:50

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T16:39:47', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'd49ce8b2-0167-428b-9215-d854fec25775'	System	01 Oct 2020 21:39:50
User entered '01 Oct 2020 16:39'	System	01 Oct 2020 21:39:50

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 16:24'	System	01 Oct 2020 21:26:26

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 18:54'	System	01 Oct 2020 21:26:26

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 21:26:26
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:59:33

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T20:42:45', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '9745f420-10cf-4201-a49f-7bdac0c1dbc8'	System	02 Oct 2020 01:43:01
User entered 'None (1)'	System	02 Oct 2020 01:43:01



US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:59:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T20:42:48', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '9745f420-10cf-4201-a49f-7bdac0c1dbc8'	System	02 Oct 2020 01:43:01
User entered 'No (N)'	System	02 Oct 2020 01:43:01

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:59:33

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T20:42:53', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '9745f420-10cf-4201-a49f-7bdac0c1dbc8'	System	02 Oct 2020 01:43:01
User entered 'No (N)'	System	02 Oct 2020 01:43:01

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:59:33

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T20:42:56', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '9745f420-10cf-4201-a49f-7bdac0c1dbc8'	System	02 Oct 2020 01:43:01
User entered 'None (1)'	System	02 Oct 2020 01:43:01

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T20:42:58', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '9745f420-10cf-4201-a49f-7bdac0c1dbc8'	System	02 Oct 2020 01:43:01
User entered '01 Oct 2020 20:42'	System	02 Oct 2020 01:43:01

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 19:49'	System	01 Oct 2020 21:26:26

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 21:26:26

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 21:26:26
User entered 'Day 2'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:59:33

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-02T12:00:50', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '2e4af1d4-2ba1-40ab-85a2-f844b8164878'	System	02 Oct 2020 17:01:43
User entered 'None (1)'	System	02 Oct 2020 17:01:43



**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:59:33**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-02T12:00:59', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '2e4af1d4-2ba1-40ab-85a2-f844b8164878'	System	02 Oct 2020 17:01:43
User entered 'No (N)'	System	02 Oct 2020 17:01:43

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:59:33

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-02T12:01:02', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '2e4af1d4-2ba1-40ab-85a2-f844b8164878'	System	02 Oct 2020 17:01:43
User entered 'No (N)'	System	02 Oct 2020 17:01:43

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:59:33

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-02T12:01:07', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '2e4af1d4-2ba1-40ab-85a2-f844b8164878'	System	02 Oct 2020 17:01:43
User entered 'None (1)'	System	02 Oct 2020 17:01:43

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-02T12:01:10', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '2e4af1d4-2ba1-40ab-85a2-f844b8164878' User entered '02 Oct 2020 12:01'	System	02 Oct 2020 17:01:43
	System	02 Oct 2020 17:01:43

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 21:26:26

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 21:26:26

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 21:26:26
User entered 'Day 3'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:59:33

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-03T12:10:52', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '64de8512-7440-4b6a-a33d-af3e856adcc6'	System	03 Oct 2020 17:11:07
User entered 'None (1)'	System	03 Oct 2020 17:11:07



US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:59:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-03T12:10:57', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '64de8512-7440-4b6a-a33d-af3e856adcc6'	System	03 Oct 2020 17:11:07
User entered 'No (N)'	System	03 Oct 2020 17:11:07

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:59:33

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-03T12:11:00', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '64de8512-7440-4b6a-a33d-af3e856adcc6'	System	03 Oct 2020 17:11:07
User entered 'No (N)'	System	03 Oct 2020 17:11:07

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:59:33

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-03T12:11:02', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '64de8512-7440-4b6a-a33d-af3e856adcc6' User entered 'None (1)'	System	03 Oct 2020 17:11:07
	System	03 Oct 2020 17:11:07

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-03T12:11:04', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '64de8512-7440-4b6a-a33d-af3e856adcc6'	System	03 Oct 2020 17:11:07
User entered '03 Oct 2020 12:11'	System	03 Oct 2020 17:11:07

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 21:26:26

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 21:26:26

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 21:26:26
User entered 'Day 4'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:59:33

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-04T20:38:34', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '6f166518-2e7a-4c1c-a369-d68f22ca8c70'	System	05 Oct 2020 01:38:48
User entered 'None (1)'	System	05 Oct 2020 01:38:48



US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:59:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-04T20:38:38', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '6f166518-2e7a-4c1c-a369-d68f22ca8c70'	System	05 Oct 2020 01:38:48
User entered 'No (N)'	System	05 Oct 2020 01:38:48

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:59:33

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-04T20:38:41', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '6f166518-2e7a-4c1c-a369-d68f22ca8c70'	System	05 Oct 2020 01:38:48
User entered 'No (N)'	System	05 Oct 2020 01:38:48

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:59:33

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-04T20:38:44', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '6f166518-2e7a-4c1c-a369-d68f22ca8c70'	System	05 Oct 2020 01:38:48
User entered 'None (1)'	System	05 Oct 2020 01:38:48

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-04T20:38:47', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '6f166518-2e7a-4c1c-a369-d68f22ca8c70' User entered '04 Oct 2020 20:38'	System	05 Oct 2020 01:38:48
	System	05 Oct 2020 01:38:48

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 21:26:26

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 21:26:26

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 21:26:26
User entered 'Day 5'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:59:33

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-05T13:18:45', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '4a9673ca-6443-4e93-9460-626d1c8674aa'	System	05 Oct 2020 18:18:56
User entered 'None (1)'	System	05 Oct 2020 18:18:56



US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:59:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-05T13:18:47', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '4a9673ca-6443-4e93-9460-626d1c8674aa' User entered 'No (N)'	System	05 Oct 2020 18:18:56
	System	05 Oct 2020 18:18:56

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:59:33

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-05T13:18:49', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '4a9673ca-6443-4e93-9460-626d1c8674aa' User entered 'No (N)'	System	05 Oct 2020 18:18:56

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:59:33

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-05T13:18:51', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '4a9673ca-6443-4e93-9460-626d1c8674aa'	System	05 Oct 2020 18:18:56
User entered 'None (1)'	System	05 Oct 2020 18:18:56

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-05T13:18:53', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '4a9673ca-6443-4e93-9460-626d1c8674aa' User entered '05 Oct 2020 13:18'	System	05 Oct 2020 18:18:56
	System	05 Oct 2020 18:18:56

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 21:26:26

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 21:26:26

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 21:26:26
User entered 'Day 6'	System	01 Oct 2020 21:26:26

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:59:33

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-06T20:33:22', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '32a331f3-1d11-4800-af5a-0eb92f6bde85'	System	07 Oct 2020 01:33:31
User entered 'None (1)'	System	07 Oct 2020 01:33:31



US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:59:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-06T20:33:24', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '32a331f3-1d11-4800-af5a-0eb92f6bde85'	System	07 Oct 2020 01:33:31
User entered 'No (N)'	System	07 Oct 2020 01:33:31

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:59:33

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-06T20:33:25', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '32a331f3-1d11-4800-af5a-0eb92f6bde85'	System	07 Oct 2020 01:33:31
User entered 'No (N)'	System	07 Oct 2020 01:33:31

US3342199

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:59:33

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-06T20:33:27', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '32a331f3-1d11-4800-af5a-0eb92f6bde85'	System	07 Oct 2020 01:33:31
User entered 'None (1)'	System	07 Oct 2020 01:33:31

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-06T20:33:29', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '32a331f3-1d11-4800-af5a-0eb92f6bde85'	System	07 Oct 2020 01:33:31
User entered '06 Oct 2020 20:33'	System	07 Oct 2020 01:33:31

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 21:26:26

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 21:26:26

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 21:26:26
User entered 'Day 7'	System	01 Oct 2020 21:26:26

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 21:26:26



**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 21:26:26

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 21:26:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 21:26:26

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:33**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T16:39:52', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '133261f8-c942-4b34-9c74-c46b36de4915' User entered 'None (0)'	System	01 Oct 2020 21:40:11

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:33**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T16:39:54', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '133261f8-c942-4b34-9c74-c46b36de4915' User entered 'None (0)'	System	01 Oct 2020 21:40:11
	System	01 Oct 2020 21:40:11

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:33**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T16:39:56', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '133261f8-c942-4b34-9c74-c46b36de4915'	System	01 Oct 2020 21:40:11
User entered 'None (0)'	System	01 Oct 2020 21:40:11

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:33**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T16:39:58', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '133261f8-c942-4b34-9c74-c46b36de4915' User entered 'None (0)'	System	01 Oct 2020 21:40:11
	System	01 Oct 2020 21:40:11

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:33**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T16:40:00', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '133261f8-c942-4b34-9c74-c46b36de4915'	System	01 Oct 2020 21:40:11
User entered 'None (0)'	System	01 Oct 2020 21:40:11

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:33**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T16:40:01', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '133261f8-c942-4b34-9c74-c46b36de4915' User entered 'None (0)'	System	01 Oct 2020 21:40:11
	System	01 Oct 2020 21:40:11



US3342199

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:59:33

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T16:40:05', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '133261f8-c942-4b34-9c74-c46b36de4915' User entered 'No (N)'	System	01 Oct 2020 21:40:11

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T16:40:07', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '133261f8-c942-4b34-9c74-c46b36de4915'	System	01 Oct 2020 21:40:11
User entered '01 Oct 2020 16:40'	System	01 Oct 2020 21:40:11

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 16:24'	System	01 Oct 2020 21:26:26

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 18:54'	System	01 Oct 2020 21:26:26

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 21:26:26
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 21:26:26

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:33**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T20:43:01', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '53812bee-77b0-44a7-94f2-807579e4b83c' User entered 'None (0)'	System	02 Oct 2020 01:43:20
	System	02 Oct 2020 01:43:20

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:33**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T20:43:04', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '53812bee-77b0-44a7-94f2-807579e4b83c'	System	02 Oct 2020 01:43:20
User entered 'None (0)'	System	02 Oct 2020 01:43:20

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:33**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T20:43:07', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '53812bee-77b0-44a7-94f2-807579e4b83c'	System	02 Oct 2020 01:43:20
User entered 'None (0)'	System	02 Oct 2020 01:43:20



**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:33**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T20:43:08', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '53812bee-77b0-44a7-94f2-807579e4b83c' User entered 'None (0)'	System	02 Oct 2020 01:43:20
	System	02 Oct 2020 01:43:20

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:33**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T20:43:11', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '53812bee-77b0-44a7-94f2-807579e4b83c'	System	02 Oct 2020 01:43:20
User entered 'None (0)'	System	02 Oct 2020 01:43:20

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:33**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T20:43:13', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '53812bee-77b0-44a7-94f2-807579e4b83c' User entered 'None (0)'	System	02 Oct 2020 01:43:20
	System	02 Oct 2020 01:43:20

US3342199

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:59:33

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T20:43:15', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '53812bee-77b0-44a7-94f2-807579e4b83c'	System	02 Oct 2020 01:43:20
User entered 'No (N)'	System	02 Oct 2020 01:43:20

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-01T20:43:17', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '53812bee-77b0-44a7-94f2-807579e4b83c' User entered '01 Oct 2020 20:43'	System	02 Oct 2020 01:43:20
	System	02 Oct 2020 01:43:20

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 19:49'	System	01 Oct 2020 21:26:26

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 21:26:26

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 21:26:26
User entered 'Day 2'	System	01 Oct 2020 21:26:26



**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:59:33**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-02T12:01:13', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b04383cc-d66b-47bf-a6c6-af9d72eb77ee'	System	02 Oct 2020 17:02:09
User entered 'None (0)'	System	02 Oct 2020 17:02:09

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:59:33**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-02T12:01:15', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b04383cc-d66b-47bf-a6c6-af9d72eb77ee'	System	02 Oct 2020 17:02:09
User entered 'None (0)'	System	02 Oct 2020 17:02:09

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:59:33**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-02T12:01:17', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b04383cc-d66b-47bf-a6c6-af9d72eb77ee'	System	02 Oct 2020 17:02:09
User entered 'None (0)'	System	02 Oct 2020 17:02:09

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:59:33**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-02T12:01:19', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b04383cc-d66b-47bf-a6c6-af9d72eb77ee'	System	02 Oct 2020 17:02:09
User entered 'None (0)'	System	02 Oct 2020 17:02:09

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:59:33**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-02T12:01:20', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b04383cc-d66b-47bf-a6c6-af9d72eb77ee'	System	02 Oct 2020 17:02:09
User entered 'None (0)'	System	02 Oct 2020 17:02:09

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:59:33**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-02T12:01:22', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b04383cc-d66b-47bf-a6c6-af9d72eb77ee' User entered 'None (0)'	System	02 Oct 2020 17:02:09
	System	02 Oct 2020 17:02:09

US3342199

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:59:33

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-02T12:01:26', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b04383cc-d66b-47bf-a6c6-af9d72eb77ee'	System	02 Oct 2020 17:02:09
User entered 'No (N)'	System	02 Oct 2020 17:02:09

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-02T12:01:28', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b04383cc-d66b-47bf-a6c6-af9d72eb77ee' User entered '02 Oct 2020 12:01'	System	02 Oct 2020 17:02:09
	System	02 Oct 2020 17:02:09



**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 21:26:26

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 21:26:26

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 21:26:26
User entered 'Day 3'	System	01 Oct 2020 21:26:26

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:59:33**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-03T12:11:09', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b5a4639e-dd9b-42f4-ac4a-b0345de556a1' User entered 'None (0)'	System	03 Oct 2020 17:11:31
	System	03 Oct 2020 17:11:31

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:59:33**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-03T12:11:11', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b5a4639e-dd9b-42f4-ac4a-b0345de556a1' User entered 'None (0)'	System	03 Oct 2020 17:11:31
	System	03 Oct 2020 17:11:31

US3342199

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:59:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-03T12:11:13', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b5a4639e-dd9b-42f4-ac4a-b0345de556a1' User entered 'None (0)'	System	03 Oct 2020 17:11:31
	System	03 Oct 2020 17:11:31

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:59:33**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-03T12:11:16', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b5a4639e-dd9b-42f4-ac4a-b0345de556a1' User entered 'None (0)'	System	03 Oct 2020 17:11:31
	System	03 Oct 2020 17:11:31

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:59:33**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-03T12:11:18', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b5a4639e-dd9b-42f4-ac4a-b0345de556a1' User entered 'None (0)'	System	03 Oct 2020 17:11:31
	System	03 Oct 2020 17:11:31



**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:59:33**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-03T12:11:19', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b5a4639e-dd9b-42f4-ac4a-b0345de556a1' User entered 'None (0)'	System	03 Oct 2020 17:11:31
	System	03 Oct 2020 17:11:31

US3342199

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:59:33

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-03T12:11:23', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b5a4639e-dd9b-42f4-ac4a-b0345de556a1' User entered 'No (N)'	System	03 Oct 2020 17:11:31

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-03T12:11:25', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'b5a4639e-dd9b-42f4-ac4a-b0345de556a1'	System	03 Oct 2020 17:11:31
User entered '03 Oct 2020 12:11'	System	03 Oct 2020 17:11:31

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 21:26:26

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 21:26:26

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 21:26:26
User entered 'Day 4'	System	01 Oct 2020 21:26:26

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:59:33**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-04T20:38:50', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '21e27dc9-a40f-421a-914c-2927e1b49941'	System	05 Oct 2020 01:39:07
User entered 'None (0)'	System	05 Oct 2020 01:39:07

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:59:33**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-04T20:38:52', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '21e27dc9-a40f-421a-914c-2927e1b49941' User entered 'None (0)'	System	05 Oct 2020 01:39:07



**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:59:33**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-04T20:38:55', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '21e27dc9-a40f-421a-914c-2927e1b49941'	System	05 Oct 2020 01:39:07
User entered 'None (0)'	System	05 Oct 2020 01:39:07

US3342199

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:59:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-04T20:38:57', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '21e27dc9-a40f-421a-914c-2927e1b49941'	System	05 Oct 2020 01:39:07
User entered 'None (0)'	System	05 Oct 2020 01:39:07

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:59:33**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-04T20:38:58', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '21e27dc9-a40f-421a-914c-2927e1b49941'	System	05 Oct 2020 01:39:07
User entered 'None (0)'	System	05 Oct 2020 01:39:07

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:59:33**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-04T20:39:00', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '21e27dc9-a40f-421a-914c-2927e1b49941'	System	05 Oct 2020 01:39:07
User entered 'None (0)'	System	05 Oct 2020 01:39:07

US3342199

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:59:33

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-04T20:39:02', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '21e27dc9-a40f-421a-914c-2927e1b49941' User entered 'No (N)'	System	05 Oct 2020 01:39:07

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-04T20:39:04', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '21e27dc9-a40f-421a-914c-2927e1b49941'	System	05 Oct 2020 01:39:07
User entered '04 Oct 2020 20:39'	System	05 Oct 2020 01:39:07

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 21:26:26

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 21:26:26



**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 21:26:26
User entered 'Day 5'	System	01 Oct 2020 21:26:26

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:59:33**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-05T13:18:56', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'a2d6e949-5ada-4861-8856-4b64e7607f05'	System	05 Oct 2020 18:19:12
User entered 'None (0)'	System	05 Oct 2020 18:19:12

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:59:33**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-05T13:18:57', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'a2d6e949-5ada-4861-8856-4b64e7607f05'	System	05 Oct 2020 18:19:12
User entered 'None (0)'	System	05 Oct 2020 18:19:12

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:59:33**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-05T13:18:59', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'a2d6e949-5ada-4861-8856-4b64e7607f05'	System	05 Oct 2020 18:19:12
User entered 'None (0)'	System	05 Oct 2020 18:19:12

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:59:33**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-05T13:19:00', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'a2d6e949-5ada-4861-8856-4b64e7607f05'	System	05 Oct 2020 18:19:12
User entered 'None (0)'	System	05 Oct 2020 18:19:12

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:59:33**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-05T13:19:03', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'a2d6e949-5ada-4861-8856-4b64e7607f05'	System	05 Oct 2020 18:19:12
User entered 'None (0)'	System	05 Oct 2020 18:19:12

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:59:33**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-05T13:19:04', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'a2d6e949-5ada-4861-8856-4b64e7607f05'	System	05 Oct 2020 18:19:12
User entered 'None (0)'	System	05 Oct 2020 18:19:12

US3342199

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:59:33

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-05T13:19:09', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'a2d6e949-5ada-4861-8856-4b64e7607f05'	System	05 Oct 2020 18:19:12
User entered 'No (N)'	System	05 Oct 2020 18:19:12



**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-05T13:19:10', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'a2d6e949-5ada-4861-8856-4b64e7607f05'	System	05 Oct 2020 18:19:12
User entered '05 Oct 2020 13:19'	System	05 Oct 2020 18:19:12

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 21:26:26

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 21:26:26

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 21:26:26
User entered 'Day 6'	System	01 Oct 2020 21:26:26

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:59:33**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-06T20:33:32', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'be7f8784-1550-4b81-b2bd-68091a5bb4d9'	System	07 Oct 2020 01:33:44
User entered 'None (0)'	System	07 Oct 2020 01:33:44

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:59:33**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-06T20:33:33', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'be7f8784-1550-4b81-b2bd-68091a5bb4d9'	System	07 Oct 2020 01:33:44
User entered 'None (0)'	System	07 Oct 2020 01:33:44

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:59:33**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-06T20:33:35', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'be7f8784-1550-4b81-b2bd-68091a5bb4d9'	System	07 Oct 2020 01:33:44
User entered 'None (0)'	System	07 Oct 2020 01:33:44

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:59:33**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-06T20:33:36', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'be7f8784-1550-4b81-b2bd-68091a5bb4d9'	System	07 Oct 2020 01:33:44
User entered 'None (0)'	System	07 Oct 2020 01:33:44



**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:59:33**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-06T20:33:38', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'be7f8784-1550-4b81-b2bd-68091a5bb4d9'	System	07 Oct 2020 01:33:44
User entered 'None (0)'	System	07 Oct 2020 01:33:44

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:59:33**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-06T20:33:39', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'be7f8784-1550-4b81-b2bd-68091a5bb4d9'	System	07 Oct 2020 01:33:44
User entered 'None (0)'	System	07 Oct 2020 01:33:44

US3342199

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:59:33

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-06T20:33:41', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'be7f8784-1550-4b81-b2bd-68091a5bb4d9'	System	07 Oct 2020 01:33:44
User entered 'No (N)'	System	07 Oct 2020 01:33:44

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-10-06T20:33:43', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: 'be7f8784-1550-4b81-b2bd-68091a5bb4d9' User entered '06 Oct 2020 20:33'	System	07 Oct 2020 01:33:44
	System	07 Oct 2020 01:33:44

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 21:26:26

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 21:26:26

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 21:26:26
User entered 'Day 7'	System	01 Oct 2020 21:26:26

**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 21:26:26



**US3342199**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:59:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 21:26:26

**US3342199**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:59:33**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 18:30:10

**US3342199**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:59:33**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '8 Oct 2020'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 18:30:10

**US3342199**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:59:33**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 18:30:10

**US3342199**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:59:33**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 18:30:10

US3342199

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 18:30:15

**US3342199**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:59:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Oct 2020 18:30:15

**US3342199**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:59:33**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 15:03:49



US3342199

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:33

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 15:03:49

**US3342199**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:59:33**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	16 Oct 2020 15:03:49

**US3342199**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:59:33**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 15:03:49

US3342199

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 15:03:54

**US3342199**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:59:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Oct 2020 15:03:54

US3342199

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Oct 2020 15:55:14

**US3342199**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:59:33**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Oct 2020'	(b) (4), (b) (6)	23 Oct 2020 15:55:14

US3342199

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	23 Oct 2020 15:55:14



**US3342199**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:59:33**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 15:55:14

US3342199

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Oct 2020 15:55:18

**US3342199**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:59:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Oct 2020 15:55:18

**US3342199**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:59:33**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 19:39:51

**US3342199**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:59:33**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '28 Oct 2020'	(b) (4), (b) (6)	28 Oct 2020 19:39:51

**US3342199**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:59:33**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	28 Oct 2020 19:39:51

**US3342199**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:59:33**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	28 Oct 2020 19:39:51

US3342199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 19:40:38



US3342199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Oct 2020'	(b) (4), (b) (6)	28 Oct 2020 19:40:38

US3342199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:33

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User entered '14:06'	(b) (4), (b) (6)	28 Oct 2020 19:40:38

**US3342199**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:59:33**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '28 Oct 2020 14:06'	System	28 Oct 2020 19:40:38

US3342199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:33

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.7' F	(b) (4), (b) (6)	28 Oct 2020 19:40:38

US3342199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:33

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	28 Oct 2020 19:40:38

US3342199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:33

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 19:40:38

US3342199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '60'	(b) (4), (b) (6)	28 Oct 2020 19:40:38

**US3342199**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:59:33**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	28 Oct 2020 19:40:38



US3342199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '14'	(b) (4), (b) (6)	28 Oct 2020 19:40:38

US3342199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	28 Oct 2020 19:40:38

US3342199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '146'	(b) (4), (b) (6)	28 Oct 2020 19:40:38

**US3342199**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:59:33**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Oct 2020 19:40:38

US3342199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '90'	(b) (4), (b) (6)	28 Oct 2020 19:40:38

US3342199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:33

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Oct 2020 19:40:38

US3342199

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:59:33

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	28 Oct 2020 19:41:02

US3342199

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:59:33

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 19:41:02



US3342199

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:59:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	29 Oct 2020 14:39:38

US3342199

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:59:33

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit 3 Day 57 is recorded as 28-OCT-2020. However, collection date is missing in GCL. Please confirm if 28-OCT-2020 is correct date to update in GCL records.' answered with 'collection date was 28OCT2020' (Site from DM).	Eileen Euperio (b) (4) (b) (4)	10 Nov 2020 22:56:09
User opened query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit 3 Day 57 is recorded as 28-OCT-2020. However, collection date is missing in GCL. Please confirm if 28-OCT-2020 is correct date to update in GCL records.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 09:32:48
User entered '28 Oct 2020'	Morgan Schulle (b) (4) (b) (4)	29 Oct 2020 14:39:38

US3342199

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:59:33

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '14:47'	Morgan Schulle (b) (4) (b) (4)	29 Oct 2020 14:39:38

**US3342199**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:59:33**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '28 Oct 2020 14:47'	System	29 Oct 2020 14:39:38

US3342199

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 19:41:06

**US3342199**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:59:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	28 Oct 2020 19:41:06

**US3342199**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:37:32
User entered 'Day 64'	System	04 Sep 2020 20:37:32

**US3342199**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-11-06T12:00:53', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '80938f7f-5d09-473b-9d40-dbb4cc589304'	System	06 Nov 2020 18:01:39
User entered 'No (N)'	System	06 Nov 2020 18:01:39



**US3342199**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-11-06T12:01:05', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '80938f7f-5d09-473b-9d40-dbb4cc589304'	System	06 Nov 2020 18:01:39
User entered 'No (N)'	System	06 Nov 2020 18:01:39

**US3342199**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (80F80350-40C0-450B-A766-FAE2C75174BE)', Time: '2020-11-06T12:01:09', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '80938f7f-5d09-473b-9d40-dbb4cc589304' User entered '06 Nov 2020 12:01:09'	System	06 Nov 2020 18:01:39
	System	06 Nov 2020 18:01:39

**US3342199**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:37:32
User entered '04 Nov 2020 00:01'	System	04 Sep 2020 20:37:32

**US3342199**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:37:32
User entered '08 Nov 2020 23:59'	System	04 Sep 2020 20:37:32

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '01 Nov 2020 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '05 Nov 2020 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 04:13:18



**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '08 Nov 2020 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '12 Nov 2020 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '15 Nov 2020 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '19 Nov 2020 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2020-11-23T17:18:16', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '9665e7c3-ed0e-47f0-92c4-15fd30116111'	System	23 Nov 2020 23:18:30
User entered 'No (N)'	System	23 Nov 2020 23:18:30

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2020-11-23T17:18:24', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '9665e7c3-ed0e-47f0-92c4-15fd30116111'	System	23 Nov 2020 23:18:30
User entered 'No (N)'	System	23 Nov 2020 23:18:30



**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F40FBF0A-AAE8-495D-9788-0781A7C26CCB)', Time: '2020-11-23T17:18:27', User OID: 'PatientReportedOutcome (US3342199)', ODM File OID: '9665e7c3-ed0e-47f0-92c4-15fd30116111' User entered '23 Nov 2020 17:18:27'	System	23 Nov 2020 23:18:30
	System	23 Nov 2020 23:18:30

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 04:13:18



**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 04:13:18



**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 04:13:18



**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 04:13:18



**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 04:13:18



**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 04:13:18



**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 04:13:18



**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 04:13:18



**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 04:13:18



**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 04:13:18



**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 04:13:18



**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 04:13:18



**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 04:13:18



**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 04:13:18



**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 04:13:18



**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 04:13:18



**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 04:13:18



**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 04:13:18



**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 04:13:18



**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 04:13:18



**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 04:13:18



**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 04:13:18



**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 04:13:18



**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 04:13:18



**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 04:13:18



**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 04:13:18



**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 04:13:18



**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 04:13:18



**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 04:13:18



**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 04:13:18



**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 04:13:18



**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 04:13:18



**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 04:13:18



**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 04:13:18



**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 04:13:18



**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 04:13:18



**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 04:13:18



**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 04:13:18



**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:18
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 04:13:18

**US3342199**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:59:33**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Nov 2020 23:20:54

**US3342199**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:59:33**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Nov 2020'	(b) (4), (b) (6)	23 Nov 2020 23:20:54

**US3342199**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:59:33**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	23 Nov 2020 23:20:54



**US3342199**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:59:33**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 23:20:54

US3342199

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Nov 2020 23:20:59

**US3342199**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:59:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Nov 2020 23:20:59

US3342199

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:59:33

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Query 'Re-query x2: Per review of AE log Headache is still not entered. Please reconcile and enter since subject didn't record in diary.' answered with 'HA did not last beyond Day 7 ' (Site from CRA).	Eileen Euperio (b) (4)	23 Nov 2020 13:59:15
User opened query 'Re-query x2: Per review of AE log Headache is still not entered. Please reconcile and enter since subject didn't record in diary.' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 04:09:17
User closed query 'Re-query: If not entered in eDiary then it must be entered in the AE log per protocol and CCGs. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 04:09:17
Query 'Re-query: If not entered in eDiary then it must be entered in the AE log per protocol and CCGs. Please reconcile.' answered with 'AE entered in AE log' (Site from CRA).	Stefanie Mott (b) (4)	18 Nov 2020 15:41:51
User opened query 'Re-query: If not entered in eDiary then it must be entered in the AE log per protocol and CCGs. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:48:02
User closed query 'Please add AE of headache noted on conmed source (06SEP2020).' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:48:02
Query 'Please add AE of headache noted on conmed source (06SEP2020).' answered with 'per source, headache is a solicited AR that was not entered in ed diary by subject in error' (Site from CRA).	Eileen Euperio (b) (4)	02 Oct 2020 18:42:30
User opened query 'Please add AE of headache noted on conmed source (06SEP2020).' (Site from CRA).	(b) (4), (b) (6)	01 Oct 2020 16:08:01
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:31:01
User entered 'Yes (Y)'	Eileen Euperio (b) (4)	18 Sep 2020 19:25:18

US3342199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:33

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:04:01
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:06
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:04
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:57:09
User entered 'USA-US203-2020-mRNA-1273-P301000002'	System	20 Sep 2020 17:57:05
User entered 'New'	(b) (4), (b) (6)	20 Sep 2020 17:57:05

US3342199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:33

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 05:15:52
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal inflammatory conditions, HLT: Colitis (excl infective), PT: Colitis, LLT: Colitis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 21:13:29
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 21:13:29
Data point term sent to Coder	System	09 Oct 2020 20:24:44
Coding entries removed.	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:24:16
User entered 'ACUTE FOCAL COLITIS' reason for change: New Information	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:24:16
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Diverticulitis, LLT: Diverticulitis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 20:55:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 20:55:54
Data point term sent to Coder	System	01 Oct 2020 20:54:25
DataPoint Un-verified.	Morgan Schulle (b) (4) (b) (4)	01 Oct 2020 20:54:11
Coding entries removed.	Morgan Schulle (b) (4) (b) (4)	01 Oct 2020 20:54:11
User entered 'DIVERTICULITIS' reason for change: Data Entry Error	Morgan Schulle (b) (4) (b) (4)	01 Oct 2020 20:54:11
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:04:01
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal inflammatory conditions, HLT: Colitis (excl infective), PT: Colitis, LLT: Colitis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Sep 2020 05:15:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Sep 2020 05:15:48
Data point term sent to Coder	System	18 Sep 2020 19:43:04
User entered 'colitis-unspecified'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:42:05

**US3342199**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:59:33**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:04:01
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:42:05

**US3342199**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:59:33**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:04:01
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:42:05



**US3342199**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:59:33**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:04:01
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:42:05

**US3342199**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:59:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:04:01
User entered '13 Sep 2020'	Eileen Euperio (b) (4)	18 Sep 2020 19:42:05
	(b) (4)	

**US3342199**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:59:33**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:04:01
User entered empty.	Eileen Euperio (b) (4)	18 Sep 2020 19:42:05
	(b) (4)	

**US3342199**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:59:33**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 19:42:05

**US3342199**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:59:33**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:04:01
User entered 'No (N)' reason for change: Data Entry Error	Eileen Euperio (b) (4)	28 Sep 2020 23:29:29
User entered 'Yes (Y)'	Eileen Euperio (b) (4)	18 Sep 2020 19:42:05

US3342199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:33

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:04:01
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	29 Sep 2020 14:48:54
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'UPDATED' (Site from Safety).	Eileen Euperio (b) (4)	28 Sep 2020 23:29:35
User entered '25 Sep 2020' reason for change: Data Entry Error	(b) (4)	28 Sep 2020 23:29:29
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 15:52:17
User entered empty.	Eileen Euperio (b) (4)	18 Sep 2020 19:42:05

**US3342199**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:59:33**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:04:01
User entered empty.	Eileen Euperio (b) (4)	18 Sep 2020 19:42:05
	(b) (4)	

**US3342199**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:59:33**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 19:42:05



US3342199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:33

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:04:01
User closed query 'PV Query: Since the subject was hospitalized for the event of colitis unspecified, appropriate severity grade should be grade 3 instead of grade 2. Please update the event severity as such. If the severity is to remain grade 2, please clarify/explain.' (Site from Safety).	(b) (4), (b) (6)	01 Oct 2020 12:08:18
Query 'PV Query: Since the subject was hospitalized for the event of colitis unspecified, appropriate severity grade should be grade 3 instead of grade 2. Please update the event severity as such. If the severity is to remain grade 2, please clarify/explain.' answered with 'updated' (Site from Safety).	Eileen Euperio (b) (4)	30 Sep 2020 13:35:35
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	(b) (4)	30 Sep 2020 13:35:30
User opened query 'PV Query: Since the subject was hospitalized for the event of colitis unspecified, appropriate severity grade should be grade 3 instead of grade 2. Please update the event severity as such. If the severity is to remain grade 2, please clarify/explain.' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 15:54:14
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Eileen Euperio (b) (4)	18 Sep 2020 19:42:05
	(b) (4)	

US3342199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:33

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:04:01
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 19:42:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Sep 2020 19:42:21
User entered 'Yes (Y)' reason for change: Data Entry Error	Eileen Euperio (b) (4)	18 Sep 2020 19:42:21
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 19:42:05
User entered empty.	Eileen Euperio (b) (4)	18 Sep 2020 19:42:05

**US3342199**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:59:33**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:04:01
User entered '0'	Eileen Euperio (b) (4)	18 Sep 2020 19:42:05
	(b) (4)	

**US3342199**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:59:33**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:04:01
User entered '0'	Eileen Euperio (b) (4)	18 Sep 2020 19:42:05
	(b) (4)	

**US3342199**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:59:33**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:04:01
User entered '1'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:42:05

**US3342199**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:59:33**

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:04:01
User entered '13 Sep 2020'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:42:05

**US3342199**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:59:33**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:04:01
User entered '15 Sep 2020'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:42:05

**US3342199**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:59:33**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:04:01
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:42:05



**US3342199**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:59:33**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:04:01
User entered empty.	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:42:05

**US3342199**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:59:33**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:04:01
User entered '0'	Eileen Euperio (b) (4)	18 Sep 2020 19:42:05
	(b) (4)	

**US3342199**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:59:33**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:04:01
User entered '0'	Eileen Euperio (b) (4)	18 Sep 2020 19:42:05
	(b) (4)	

**US3342199**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:59:33**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:04:01
User entered '0'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:42:05

**US3342199**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:59:33**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:04:01
User entered 'Not Related (NOT RELATED)'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:42:05

**US3342199**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:59:33**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:04:01
User entered 'Not Related (NOT RELATED)'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:42:05

**US3342199**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:59:33**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:04:01
User entered 'None (NONE)'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:42:05

**US3342199**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:59:33**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:04:01
User entered '0'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:42:05



**US3342199**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:59:33**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:04:01
User entered '1'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:42:05

**US3342199**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:59:33**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:04:01
User entered '0'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:42:05

US3342199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:33

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:04:01
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	01 Oct 2020 12:08:30
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	Eileen Euperio (b) (4)	30 Sep 2020 13:35:42
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	28 Sep 2020 23:29:29
Data Entry Error		
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 15:52:36
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 19:42:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Sep 2020 19:42:34
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change:	Eileen Euperio (b) (4)	18 Sep 2020 19:42:34
Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 19:42:05
User entered empty.	Eileen Euperio (b) (4)	18 Sep 2020 19:42:05
	(b) (4)	

**US3342199**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:59:33**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:04:01
User entered empty.	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:42:05

US3342199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:33

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: SAE Narrative = CT OF ABDOMEN/PELVIS, CBC LABS and ROUTINE CHEMISTRY noted. However, these were not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 21:01:53
Query 'Per DM CLR: SAE Narrative = CT OF ABDOMEN/PELVIS, CBC LABS and ROUTINE CHEMISTRY noted. However, these were not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'added labs and CT to conproc. CRF' (Site from DM).	Eileen Euperio (b) (4) (b) (4)	18 Nov 2020 19:48:41
User opened query 'Per DM CLR: SAE Narrative = CT OF ABDOMEN/PELVIS, CBC LABS and ROUTINE CHEMISTRY noted. However, these were not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 10:37:44
User closed query 'PV Query: Please provide results of stool cultures, if done.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 14:15:51
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 14:15:48
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 14:15:43
Query 'PV Query: Please provide results of stool cultures, if done.' answered with 'stool cultures not documented in med records' (Site from Safety).	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:09:10
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'updated narrative' (Site from Safety).	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:08:31

US3342199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:33

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'updated narrative' (Site from Safety). DataPoint Un-verified.	Eileen Euperio (b) (4)	09 Oct 2020 20:08:27
	Eileen Euperio (b) (4)	09 Oct 2020 20:08:11
User entered 'SUBJECT WENT TO HOSPITAL ON 13SEP2020 FOR ABDOMINAL PAIN AND FEVER. ADMITTED, CT SCAN DONE, DX COLITIS. GIVEN ANTIBIOTICS. RELEASED FROM HOSPITAL ON 15SEP2020.SUBJECT WENT TO HOSPITAL ON 13SEP2020 FOR ABDOMINAL PAIN AND FEVER. ADMITTED, CT SCAN DONE, DX COLITIS. GIVEN ANTIBIOTICS. RELEASED FROM HOSPITAL ON 15SEP2020. CT of abdomen/pelvic showed 3cm segment of circumferential bowel wall thickening in the sigmoid colon with significant periserosal inflammatory changes along its mesenteric side, worrisome for malignancy. Diagnostic considerations also include focal colitis. CBC labs show elevated WBC at 14.4 thou/cu mm on day of admittance 9/13/2020, back to normal values of 9.3 and 7.4 thou/cu mm on 9/14/2020 and 9/15/2020 respectively. RBC levels low at 4.05, 3.75 and 3.52 mlll/cu mm; Hgb 13.4, 12.4, 11.8 g/dL, Hct 38.3, 36.0, 34.6 percent, MCV high at 94.6, 96.0, 98.3 fL, MCH high at 33.1, 33.1, 33.5 pg, on 9/13/2020, 9/14/2020, and 9/15/2020. Differential panel show high neutro auto 76.8 and 69.8 percent, and lymph auto low at 13.5 and 18.7 percent, on 9/13/2020 and 9/15/2020. UA all in normal range on 9/13/2020. Routine chemistry showed high glucose on 9/13/2020 at 118mg/dL. Glucose levels were 98 and 92 mg/dL on 9/14/2020 and 9/15/2020. SARSCOV2 testing done on /13/2020, target nucleic acids not detected.'	Eileen Euperio (b) (4)	09 Oct 2020 20:08:11
reason for change: Data Entry Error		
User opened query 'PV Query: Please provide results of stool cultures, if done.' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 17:06:37

US3342199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:33

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 17:06:30
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 17:06:21
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:04:01
User closed query 'PV Query: Please report if the patient has any risk factors for developing colitis, including autoimmune etiologies, immunocompromised, etc.' (Site from Safety).	(b) (4), (b) (6)	01 Oct 2020 12:08:55
User closed query 'PV Query: Please provide results of stool cultures, if done.' (Site from Safety).	(b) (4), (b) (6)	01 Oct 2020 12:08:51
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	01 Oct 2020 12:08:43
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	01 Oct 2020 12:08:37
Query 'PV Query: Please report if the patient has any risk factors for developing colitis, including autoimmune etiologies, immunocompromised, etc.' answered with 'per PI, no risk factors present based on patient's current med hx' (Site from Safety).	Eileen Euperio (b) (4)	30 Sep 2020 13:54:15
Query 'PV Query: Please provide results of stool cultures, if done.' answered with 'pending medical records' (Site from Safety).	Eileen Euperio (b) (4)	30 Sep 2020 13:36:11
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'pending medical records' (Site from Safety).	Eileen Euperio (b) (4)	30 Sep 2020 13:36:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:33

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'pending medical records' (Site from Safety).	Eileen Euperio (b) (4)	30 Sep 2020 13:35:51
User opened query 'PV Query: Please report if the patient has any risk factors for developing colitis, including autoimmune etiologies, immunocompromised, etc.' (Site from Safety).	(b) (4)	
User opened query 'PV Query: Please provide results of stool cultures, if done.' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 15:55:09
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 15:54:29
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 15:52:56
User entered 'Subject went to hospital on 13Sep2020 for abdominal pain and fever. Admitted, CT scan done, Dx Colitis. Given antibiotics. Released from hospital on 15Sep2020.'	(b) (4), (b) (6)	28 Sep 2020 15:51:54
	(b) (4)	
	Eileen Euperio (b) (4)	18 Sep 2020 19:42:05
	(b) (4)	



**US3342199**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:59:33**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	18 Sep 2020 19:42:21

**US3342199**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:59:33**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	18 Sep 2020 19:42:05

**US3342199**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:59:33**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	18 Sep 2020 19:42:05

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:59:33

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User closed query 'Please enter Naproxen con med (200mg for headache taken 06SEP) from source into EDC.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:48:28
Query 'Please enter Naproxen con med (200mg for headache taken 06SEP) from source into EDC.' answered with 'data entered' (Site from CRA).	Eileen Euperio (b) (4) (b) (4)	02 Oct 2020 18:53:54
User opened query 'Please enter Naproxen con med (200mg for headache taken 06SEP) from source into EDC.' (Site from CRA).	(b) (4), (b) (6)	01 Oct 2020 15:37:17
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:31:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 20:10:07

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:59:33

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: ACICLOVIR, PRODUCTS YNonym: ACYCLOVIR [ACICLOVIR] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 20:53:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 20:53:55
Data point term sent to Coder	System	04 Sep 2020 20:34:59
User entered 'acyclovir'	(b) (4), (b) (6)	04 Sep 2020 20:34:14

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:59:33**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 20:34:14

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:59:33**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered 'herpes simplex virus type 1'	(b) (4), (b) (6)	04 Sep 2020 20:34:14

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:59:33**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered '400'	(b) (4), (b) (6)	04 Sep 2020 20:34:14



US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:59:33

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered 'mg (mg)'	(b) (4), (b) (6)	04 Sep 2020 20:34:14

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:59:33

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:34:14

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:59:33**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered 'twice daily (BID)'	(b) (4), (b) (6)	04 Sep 2020 20:34:14

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:59:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:34:14

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:59:33**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	04 Sep 2020 20:34:14

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:59:33**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:34:14

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:59:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered '24 Aug 2015'	(b) (4), (b) (6)	04 Sep 2020 20:34:14

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:59:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 20:34:14



**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:59:33**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 20:34:14

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:59:33**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:34:14

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:59:33**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 20:34:14

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:59:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	04 Sep 2020 20:34:14

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:59:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 20:34:14

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:59:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Sep 2020 20:34:14

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:59:33

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: NASAL DECONGESTANTS FOR SYSTEMIC USE, ATC: SYMPATHOMIMETICS, PRODUCT: PSEUDOEPHEDRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 20:45:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 20:45:48
Data point term sent to Coder	System	04 Sep 2020 20:44:26
User entered 'pseudoephedrine'	(b) (4), (b) (6)	04 Sep 2020 20:43:30

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:59:33

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 20:43:30



**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:59:33**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered 'seasonal allergies'	(b) (4), (b) (6)	04 Sep 2020 20:43:30

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:59:33**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered '60'	(b) (4), (b) (6)	04 Sep 2020 20:43:30

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:59:33

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered 'mg (mg)'	(b) (4), (b) (6)	04 Sep 2020 20:43:30

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:59:33

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:43:30

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:59:33**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered 'as needed (PRN)'	(b) (4), (b) (6)	04 Sep 2020 20:43:30

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:59:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:43:30

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:59:33**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	04 Sep 2020 20:43:30

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:59:33**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:43:30



**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:59:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered 'un UNK 1985'	(b) (4), (b) (6)	04 Sep 2020 20:43:30

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:59:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 20:43:30

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:59:33**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 20:43:30

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:59:33**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 20:43:30

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:59:33**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 20:43:30

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:59:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 20:43:30

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:59:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 20:43:30

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:59:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 20:43:30



US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:59:33

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: STOMATOLOGICAL PREPARATIONS, ATC: STOMATOLOGICAL PREPARATIONS, ATC: ANTIINFECTIVES AND ANTISEPTICS FOR LOCAL ORAL TREATMENT, PRODUCT: METRONIDAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 21:05:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 21:05:48
Data point term sent to Coder	System	09 Oct 2020 20:29:55
Coding entries removed.	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:29:27
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Sep 2020 06:40:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Sep 2020 06:40:46
Data point term sent to Coder	System	18 Sep 2020 19:48:21
User entered 'metronidazole'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:48:00

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:59:33**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:48:00

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:59:33

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Eileen Euperio (b) (4)	09 Oct 2020 20:29:27
	(b) (4)	
User entered 'AE ACUTE FOCAL COLITIS' reason for change: New Information	Eileen Euperio (b) (4)	09 Oct 2020 20:29:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered 'AE colitis'	Eileen Euperio (b) (4)	18 Sep 2020 19:48:00
	(b) (4)	

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:59:33

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered '500'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:48:00

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:59:33**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered 'mg (mg)'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:48:00

US3342199

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:59:33**

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered empty.	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:48:00

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:59:33

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Eileen Euperio (b) (4)	10 Nov 2020 16:56:15
	(b) (4)	
User entered 'three times daily (TID)' reason for change: Data Entry Error	Eileen Euperio (b) (4)	10 Nov 2020 16:56:15
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered 'once (ONCE)'	Eileen Euperio (b) (4)	18 Sep 2020 19:48:00
	(b) (4)	

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:59:33**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered empty.	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:48:00



**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:59:33**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered 'Oral (ORAL)'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:48:00

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:59:33**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered empty.	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:48:00

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:59:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered '13 Sep 2020'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:48:00

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:59:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered '0'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:48:00

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:59:33**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:48:00

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:59:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Un-verified.	Eileen Euperio (b) (4)	10 Nov 2020 16:56:15
	(b) (4)	
User entered '20 Sep 2020' reason for change: Data Entry Error	Eileen Euperio (b) (4)	10 Nov 2020 16:56:15
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered '13 Sep 2020'	Eileen Euperio (b) (4)	18 Sep 2020 19:48:00
	(b) (4)	

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:59:33**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered 'No (N)' reason for change: Data Entry Error	Eileen Euperio (b) (4)	18 Sep 2020 19:48:07
User entered 'Yes (Y)'	Eileen Euperio (b) (4)	18 Sep 2020 19:48:00

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:59:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	10 Nov 2020 16:56:15
User entered empty.	System	18 Sep 2020 19:48:00



**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:59:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 16:56:15
User entered empty.	System	18 Sep 2020 19:48:00

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:59:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Nov 2020 16:56:15
User entered empty.	System	18 Sep 2020 19:48:00

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:59:33

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: CIPROFLOXACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 23:06:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 23:06:25
Data point term sent to Coder Coding entries removed.	System Eileen Euperio (b) (4)	09 Oct 2020 20:29:55 09 Oct 2020 20:29:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 16:02:56
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: CIPROFLOXACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Sep 2020 05:13:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Sep 2020 05:13:47
Data point term sent to Coder User entered 'ciprofloxacin'	System Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:49:26 18 Sep 2020 19:48:53

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:59:33**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:48:53

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:59:33

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Eileen Euperio (b) (4)	09 Oct 2020 20:29:34
	(b) (4)	
User entered 'AE ACUTE FOCAL COLITIS' reason for change: Data Entry Error	Eileen Euperio (b) (4)	09 Oct 2020 20:29:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered 'AE colitis'	Eileen Euperio (b) (4)	18 Sep 2020 19:48:53
	(b) (4)	

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:59:33**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered '500'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:48:53

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:59:33

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered 'mg (mg)'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:48:53

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:59:33

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered empty.	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:48:53



**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:59:33**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered 'twice daily (BID)'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:48:53

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:59:33

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered empty.	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:48:53

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:59:33

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User closed query 'Other, specify is provided, however Route of administration is not Other. Please correct.' (Site from System).	System	18 Sep 2020 19:49:12
User opened query 'Other, specify is provided, however Route of administration is not Other. Please correct.' (Site from System).	System	18 Sep 2020 19:48:53
User entered 'Oral (ORAL)'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:48:53

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:59:33

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered empty; reason for change Data Entry Error	Eileen Euperio (b) (4)	18 Sep 2020 19:49:12
User entered '13'	(b) (4)	
	Eileen Euperio (b) (4)	18 Sep 2020 19:48:53
	(b) (4)	

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:59:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered '13 Sep 2020'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:48:53

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:59:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered '0'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:48:53

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:59:33**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered 'No (N)' reason for change: Data Entry Error	Eileen Euperio (b) (4)	28 Sep 2020 23:29:57
User entered 'Yes (Y)'	Eileen Euperio (b) (4)	18 Sep 2020 19:48:53

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:59:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered '24 Sep 2020' reason for change: Data Entry Error	Eileen Euperio (b) (4)	28 Sep 2020 23:29:57
User entered empty.	(b) (4)	
	Eileen Euperio (b) (4)	18 Sep 2020 19:48:53
	(b) (4)	



**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:59:33**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:02:56
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	18 Sep 2020 19:48:53

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:59:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	18 Sep 2020 19:48:53

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:59:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 19:48:53

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:59:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Sep 2020 19:48:53

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:59:33

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 20:56:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 20:56:51
Data point term sent to Coder	System	01 Oct 2020 20:56:29
User entered 'NAPROXEN'	Morgan Schulle (b) (4) (b) (4)	01 Oct 2020 20:56:20

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:59:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	01 Oct 2020 20:56:20

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:59:33**

[Indication](#)

Audit	User	Time (GMT)
User entered 'HEADACHE'	Morgan Schulle (b) (4) (b) (4)	01 Oct 2020 20:56:20

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:59:33

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '220'	Morgan Schulle (b) (4) (b) (4)	01 Oct 2020 20:56:20



US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:59:33

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Morgan Schulle (b) (4) (b) (4)	01 Oct 2020 20:56:20

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:59:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Morgan Schulle (b) (4) (b) (4)	01 Oct 2020 20:56:20

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:59:33

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	Morgan Schulle (b) (4) (b) (4)	01 Oct 2020 20:56:20

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:59:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Morgan Schulle (b) (4) (b) (4)	01 Oct 2020 20:56:20

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:59:33

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Morgan Schulle (b) (4) (b) (4)	01 Oct 2020 20:56:20

US3342199

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:59:33**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Morgan Schulle (b) (4) (b) (4)	01 Oct 2020 20:56:20

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:59:33

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '06 Sep 2020'	Morgan Schulle (b) (4) (b) (4)	01 Oct 2020 20:56:20

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:59:33

Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Morgan Schulle (b) (4) (b) (4)	01 Oct 2020 20:56:20



US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:59:33

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	01 Oct 2020 20:56:20

US3342199

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:59:33**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User entered '06 Sep 2020'	Morgan Schulle (b) (4) (b) (4)	01 Oct 2020 20:56:20

US3342199

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:59:33**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	01 Oct 2020 20:56:20

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:59:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 20:56:20

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:59:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 20:56:20

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:59:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 20:56:20

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:59:33

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: CODEINE;PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN;CODEINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 21:42:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 21:42:33
Data point term sent to Coder	System	09 Oct 2020 20:26:47
User entered 'ACETAMINOPHEN-CODEINE'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:26:32

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:59:33**

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:26:32



**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:59:33**

[Indication](#)

Audit	User	Time (GMT)
User entered 'AE ACUTE FOCAL COLITIS'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:26:32

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:59:33**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '300/30'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:26:32

US3342199

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:59:33**

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:26:32

US3342199

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:59:33**

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:26:32

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:59:33**

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:26:32

US3342199

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:59:33**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:26:32

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:59:33**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:26:32

US3342199

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:59:33**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:26:32



US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:59:33

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Sep 2020'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:26:32

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:59:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:26:32

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:59:33**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:26:32

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:59:33**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:26:32

US3342199

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:59:33**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:26:32

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:59:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 20:26:32

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:59:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 20:26:32

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:59:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 20:26:32



US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:59:33

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE RELATED DRUGS, PRODUCT: ZOLPIDEM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Oct 2020 20:58:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Oct 2020 20:58:26
Data point term sent to Coder	System	09 Oct 2020 20:27:47
User entered 'ZOLPIDEM'	Eileen Euperio (b) (4)	09 Oct 2020 20:27:09

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:59:33**

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:27:09

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:59:33

[Indication](#)

Audit	User	Time (GMT)
User entered 'INSOMNIA'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:27:09

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:59:33**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '5'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:27:09

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:59:33

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:27:09

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:59:33**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:27:09

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:59:33**

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:27:09

US3342199

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:59:33**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:27:09



**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:59:33**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:27:09

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:59:33**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:27:09

US3342199

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:59:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'UN UNK 2018'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:27:09

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:59:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:27:09

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:59:33**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:27:09

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:59:33**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:27:09

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:59:33**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:27:09

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:59:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 20:27:09



**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:59:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 20:27:09

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:59:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 20:27:09

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:59:33

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Oct 2020 03:51:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Oct 2020 03:51:18
Data point term sent to Coder	System	09 Oct 2020 20:28:52
User entered 'CEFTRIAXONE'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:28:01

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:59:33**

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:28:01

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:59:33**

[Indication](#)

Audit	User	Time (GMT)
User entered 'AE ACUTE FOCAL COLITIS'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:28:01

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:59:33

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DMR-Dose per administration is recorded as 'un'.Kindly consider to update response as 'Unk ' or 'unknown' else clarify.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 19:31:42
Query 'Per DMR-Dose per administration is recorded as 'un'.Kindly consider to update response as 'Unk ' or 'unknown' else clarify.' answered with 'done' (Site from DM).	Eileen Euperio (b) (4) (b) (4)	29 Oct 2020 19:41:25
User entered 'UNK' reason for change: Data Entry Error	Eileen Euperio (b) (4) (b) (4)	29 Oct 2020 19:41:16
User opened query 'Per DMR-Dose per administration is recorded as 'un'.Kindly consider to update response as 'Unk ' or 'unknown' else clarify.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 07:10:04
User entered 'UN'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:28:01

US3342199

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:59:33**

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:28:01

US3342199

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:59:33**

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered 'UNKNOWN'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:28:01



**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:59:33**

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:28:01

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:59:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:28:01

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:59:33**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intramuscular (INTRAMUSCULAR)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:28:01

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:59:33**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:28:01

US3342199

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:59:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:28:01

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:59:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:28:01

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:59:33**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:28:01

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:59:33**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User entered '14 Sep 2020'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:28:01



**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:59:33**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:28:01

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:59:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 20:28:01

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:59:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 20:28:01

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:59:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 20:28:01

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:59:33

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: PIPERACILLIN SODIUM;TAZOBACTAM SODIUM, PRODUCTSYNONYM: PIPERACILLIN/TAZOBACTAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 20:58:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 20:58:28
Data point term sent to Coder	System	09 Oct 2020 20:28:52
User entered 'PIPERACILLIN/TAZOBACTAM'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:28:37

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:59:33**

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:28:37

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:59:33

[Indication](#)

Audit	User	Time (GMT)
User entered 'AE ACUTE FOCAL COLITIS'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:28:37

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:59:33

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DMR-Dose per administration is recorded as 'UN'. Kindly consider to update 'Unknown' or UNK' .Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 16:45:07
Query 'Per DMR-Dose per administration is recorded as 'UN'. Kindly consider to update 'Unknown' or UNK' .Thank you.' answered with 'Updated to unknown.' (Site from DM).	Andrew Bell (b) (4)	06 Nov 2020 16:22:11
User entered 'UNKNOWN' reason for change: Data Entry Error	(b) (4)	06 Nov 2020 16:22:00
User opened query 'Per DMR-Dose per administration is recorded as 'UN'. Kindly consider to update 'Unknown' or UNK' .Thank you.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 07:11:28
User entered 'UN'	Eileen Euperio (b) (4)	09 Oct 2020 20:28:37



**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:59:33**

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:28:37

US3342199

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:59:33**

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered 'UNKNOWN'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:28:37

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:59:33**

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:28:37

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:59:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:28:37

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:59:33**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intravenous (INTRAVENOUS)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:28:37

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:59:33**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:28:37

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:59:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:28:37

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:59:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:28:37



**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:59:33**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:28:37

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:59:33**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User entered '13 Sep 2020'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:28:37

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:59:33**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:28:37

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:59:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 20:28:37

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:59:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 20:28:37

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 10:59:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 20:28:37

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:59:33

[Name of Medication](#)

Audit	User	Time (GMT)
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: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Oct 2020 04:02:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Oct 2020 04:02:23
Data point term sent to Coder	System	09 Oct 2020 20:29:53
User entered 'FAMOTIDINE'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:29:10

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:59:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:29:10



US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:59:33

[Indication](#)

Audit	User	Time (GMT)
User entered 'AE ACUTE FOCAL COLITIS'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:29:10

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:59:33

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DMR-Dose per administration is recorded as 'UN'. Kindly consider to update 'Unknown' or UNK' .Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 16:45:14
Query 'Per DMR-Dose per administration is recorded as 'UN'. Kindly consider to update 'Unknown' or UNK' .Thank you.' answered with 'Updated to unknown.' (Site from DM).	Andrew Bell (b) (4)	06 Nov 2020 16:22:45
User entered 'UNKNOWN' reason for change: Data Entry Error	(b) (4)	06 Nov 2020 16:22:33
User opened query 'Per DMR-Dose per administration is recorded as 'UN'. Kindly consider to update 'Unknown' or UNK' .Thank you.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 07:11:45
User entered 'UN'	Eileen Euperio (b) (4)	09 Oct 2020 20:29:10

US3342199

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:59:33**

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:29:10

US3342199

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:59:33**

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered 'UNKNOWN'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:29:10

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:59:33

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:29:10

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:59:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:29:10

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:59:33**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:29:10

US3342199

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:59:33**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:29:10



US3342199

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:59:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:29:10

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:59:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:29:10

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:59:33**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:29:10

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:59:33**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:29:10

US3342199

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:59:33**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:29:10

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:59:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 20:29:10

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:59:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 20:29:10

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 26 Nov 2020 10:59:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 20:29:10



US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:59:33

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS INHIBITING URIC ACID PRODUCTION, PRODUCT: ALLOPURINOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 21:45:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 21:45:23
Data point term sent to Coder	System	09 Oct 2020 20:31:56
User entered 'ALLOPURINOL'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:31:08

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:59:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:31:08

US3342199

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:59:33**

[Indication](#)

Audit	User	Time (GMT)
User entered 'MAINTAINENCE DRUG FOR POST PARTIAL NEPHRECTOMY'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:31:08

US3342199

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:59:33**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '100'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:31:08

US3342199

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:59:33**

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:31:08

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:59:33**

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:31:08

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:59:33

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:31:08

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:59:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:31:08



US3342199

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:59:33**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:31:08

US3342199

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:59:33**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:31:08

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:59:33

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered 'UN Sep 2019'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:31:08

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:59:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:31:08

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:59:33**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:31:08

US3342199

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:59:33**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User entered 'UN Feb 2020'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:31:08

US3342199

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:59:33**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Eileen Euperio (b) (4) (b) (4)	09 Oct 2020 20:31:08

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:59:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 20:31:08



**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:59:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 20:31:08

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 10:59:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Oct 2020 20:31:08

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:59:33

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Oct 2020 05:46:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Oct 2020 05:46:23
Data point term sent to Coder	System	23 Oct 2020 16:00:59
User entered 'Yearly Flu Vaccine'	(b) (4), (b) (6) (b) (4)	23 Oct 2020 16:00:08

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:59:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Oct 2020 16:00:08

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:59:33**

[Indication](#)

Audit	User	Time (GMT)
User entered 'Yearly Flu Prevention'	(b) (4), (b) (6)	23 Oct 2020 16:00:08

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:59:33

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '.5'	(b) (4), (b) (6)	23 Oct 2020 16:00:08

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:59:33

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mL (mL)'	(b) (4), (b) (6)	23 Oct 2020 16:00:08

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:59:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 16:00:08



US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:59:33

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	(b) (4), (b) (6)	23 Oct 2020 16:00:08

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:59:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 16:00:08

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:59:33**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	23 Oct 2020 16:00:08

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:59:33**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 16:00:08

US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:59:33

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Oct 2020'	(b) (4), (b) (6)	23 Oct 2020 16:00:08

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:59:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	23 Oct 2020 16:00:08

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:59:33**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	23 Oct 2020 16:00:08

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:59:33**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User entered '16 Oct 2020'	(b) (4), (b) (6)	23 Oct 2020 16:00:08



US3342199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:59:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	23 Oct 2020 16:00:08

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:59:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 16:00:08

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:59:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 16:00:08

**US3342199**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 26 Nov 2020 10:59:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 16:00:08

US3342199

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 26 Nov 2020 10:59:33**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	18 Nov 2020 19:31:28

**US3342199**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 26 Nov 2020 10:59:33**

**Procedure/Surgery date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Sep 2020'	Eileen Euperio (b) (4) (b) (4)	18 Nov 2020 19:47:20

US3342199

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 26 Nov 2020 10:59:33**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'CT scan abdomen/pelvis'	Eileen Euperio (b) (4) (b) (4)	18 Nov 2020 19:47:20

US3342199

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 26 Nov 2020 10:59:33**

[Indication](#)

Audit	User	Time (GMT)
User entered 'Adverse Event (AE)'	Eileen Euperio (b) (4) (b) (4)	18 Nov 2020 19:47:20



US3342199

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 26 Nov 2020 10:59:33**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	18 Nov 2020 19:47:20

US3342199

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 10:59:33

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User		Time (GMT)
User entered '15 Sep 2020' reason for change: Data Entry Error	Eileen Euperio	(b) (4)	18 Nov 2020 20:08:44
	(b) (4)		
User entered '13 Sep 2020'	Eileen Euperio	(b) (4)	18 Nov 2020 19:47:33
	(b) (4)		

**US3342199**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 26 Nov 2020 10:59:33**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'CBC labs'	Eileen Euperio (b) (4) (b) (4)	18 Nov 2020 19:47:33

US3342199

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 26 Nov 2020 10:59:33**

[Indication](#)

Audit	User	Time (GMT)
User entered 'Adverse Event (AE)'	Eileen Euperio (b) (4) (b) (4)	18 Nov 2020 19:47:33

US3342199

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 10:59:33

If indication is Other, specify

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	18 Nov 2020 19:47:33

**US3342199**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 26 Nov 2020 10:59:33**

**Procedure/Surgery date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User entered '13 Sep 2020'	Eileen Euperio (b) (4) (b) (4)	18 Nov 2020 19:48:17

**US3342199**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 26 Nov 2020 10:59:33**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'CBC LABS' reason for change: Data Entry Error	Eileen Euperio (b) (4)	18 Nov 2020 20:07:50
User entered 'routine chemistry labs'	Eileen Euperio (b) (4)	18 Nov 2020 19:48:17

**US3342199**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 26 Nov 2020 10:59:33**

[Indication](#)

Audit	User	Time (GMT)
User entered 'Adverse Event (AE)'	Eileen Euperio (b) (4) (b) (4)	18 Nov 2020 19:48:17



**US3342199**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 26 Nov 2020 10:59:33**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	18 Nov 2020 19:48:17

US3342199

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (4)**

**Generated On: 26 Nov 2020 10:59:33**

**Procedure/Surgery date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '15 Sep 2020'	Eileen Euperio (b) (4) (b) (4)	18 Nov 2020 20:13:39

US3342199

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (4)**

**Generated On: 26 Nov 2020 10:59:33**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'routine chemistry'	Eileen Euperio (b) (4) (b) (4)	18 Nov 2020 20:13:39

US3342199

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 26 Nov 2020 10:59:33

[Indication](#)

Audit	User	Time (GMT)
User entered 'Adverse Event (AE)'	Eileen Euperio (b) (4) (b) (4)	18 Nov 2020 20:13:39

US3342199

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (4)**

**Generated On: 26 Nov 2020 10:59:33**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	18 Nov 2020 20:13:39

US3342199

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (5)**

**Generated On: 26 Nov 2020 10:59:33**

**Procedure/Surgery date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '14 Sep 2020'	Eileen Euperio (b) (4) (b) (4)	18 Nov 2020 20:13:54

US3342199

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 26 Nov 2020 10:59:33

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'ROUTINE CHEMISTRY'	Eileen Euperio (b) (4) (b) (4)	18 Nov 2020 20:13:54

US3342199

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 26 Nov 2020 10:59:33

[Indication](#)

Audit	User	Time (GMT)
User entered 'Adverse Event (AE)'	Eileen Euperio (b) (4) (b) (4)	18 Nov 2020 20:13:54



US3342199

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (5)**

**Generated On: 26 Nov 2020 10:59:33**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	18 Nov 2020 20:13:54

US3342199

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (6)**

**Generated On: 26 Nov 2020 10:59:33**

**Procedure/Surgery date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Sep 2020'	Eileen Euperio (b) (4) (b) (4)	18 Nov 2020 20:14:07

US3342199

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (6)**

**Generated On: 26 Nov 2020 10:59:33**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'ROUTINE CHEMISTRY'	Eileen Euperio (b) (4) (b) (4)	18 Nov 2020 20:14:07

US3342199

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 26 Nov 2020 10:59:33

[Indication](#)

Audit	User	Time (GMT)
User entered 'Adverse Event (AE)'	Eileen Euperio (b) (4) (b) (4)	18 Nov 2020 20:14:07

US3342199

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 26 Nov 2020 10:59:33

If indication is Other, specify

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	18 Nov 2020 20:14:07

US3342199

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (7)**

**Generated On: 26 Nov 2020 10:59:33**

**Procedure/Surgery date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '25 Sep 2020'	Eileen Euperio (b) (4) (b) (4)	18 Nov 2020 20:17:33

**US3342199**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (7)**

**Generated On: 26 Nov 2020 10:59:33**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'COLONOSCOPY'	Eileen Euperio (b) (4) (b) (4)	18 Nov 2020 20:17:33

**US3342199**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (7)**

**Generated On: 26 Nov 2020 10:59:33**

[Indication](#)

Audit	User	Time (GMT)
User entered 'Adverse Event (AE)'	Eileen Euperio (b) (4) (b) (4)	18 Nov 2020 20:17:33



US3342199

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (7)**

**Generated On: 26 Nov 2020 10:59:33**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	18 Nov 2020 20:17:33

**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:33**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'USA-US203-2020-MRNA-1273-P301000002'	System	20 Sep 2020 17:57:05

**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:33**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'Yes (Y)'	System	20 Sep 2020 17:57:05

**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:33**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'No (N)'	System	20 Sep 2020 17:57:05

**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:33**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'No (N)'	System	20 Sep 2020 17:57:05

**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:33**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'Yes (Y)'	System	20 Sep 2020 17:57:05

**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:33**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'No (N)'	System	20 Sep 2020 17:57:05

**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:33**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'No (N)'	System	20 Sep 2020 17:57:05



**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:33**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'No (N)'	System	20 Sep 2020 17:57:05

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered 'PAUL'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered 'PICKRELL'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:33

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered '4534 West Gate Blvd. SUITE 110'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:33

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered 'AUSTIN'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:33

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered 'TX'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:33

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered '78745'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30

**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:33**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered 'US'	System	20 Sep 2020 18:32:50



**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:33**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	12 Oct 2020 14:17:25
User entered '4'	System	02 Oct 2020 12:31:25
User entered '3'	System	01 Oct 2020 12:09:27
User entered '2'	System	29 Sep 2020 14:49:32
User entered '1'	System	20 Sep 2020 18:32:50

**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:33**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'USA-US203-2020-MRNA-1273-P301000002'	System	20 Sep 2020 17:57:05

**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:33**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'Yes (Y)'	System	20 Sep 2020 17:57:05

**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:33**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'No (N)'	System	20 Sep 2020 17:57:05

**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:33**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'No (N)'	System	20 Sep 2020 17:57:05

**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:33**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'Yes (Y)'	System	20 Sep 2020 17:57:05

**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:33**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'No (N)'	System	20 Sep 2020 17:57:05

**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:33**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'No (N)'	System	20 Sep 2020 17:57:05



**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:33**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'No (N)'	System	20 Sep 2020 17:57:05

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered 'PAUL'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered 'PICKRELL'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:33

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered '4534 West Gate Blvd. SUITE 110'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:33

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered 'AUSTIN'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:33

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered 'TX'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:33

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered '78745'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30

**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:33**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered 'US'	System	20 Sep 2020 18:32:50



**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:33**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	12 Oct 2020 14:17:25
User entered '4'	System	02 Oct 2020 12:31:25
User entered '3'	System	01 Oct 2020 12:09:27
User entered '2'	System	29 Sep 2020 14:49:32
User entered '1'	System	20 Sep 2020 18:32:50

**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (1)**

**Generated On: 26 Nov 2020 10:59:33**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
User entered '20/Sep/2020 14:32'	System	20 Sep 2020 18:32:50

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:59:33

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered 'I'	(b) (4), (b) (6)	20 Sep 2020 18:32:50

**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:33**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'USA-US203-2020-MRNA-1273-P301000002'	System	20 Sep 2020 17:57:05

**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:33**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'Yes (Y)'	System	20 Sep 2020 17:57:05

**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:33**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'No (N)'	System	20 Sep 2020 17:57:05

**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:33**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'No (N)'	System	20 Sep 2020 17:57:05

**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:33**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'Yes (Y)'	System	20 Sep 2020 17:57:05



**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:33**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'No (N)'	System	20 Sep 2020 17:57:05

**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:33**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'No (N)'	System	20 Sep 2020 17:57:05

**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:33**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'No (N)'	System	20 Sep 2020 17:57:05

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered 'PAUL'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered 'PICKRELL'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:33

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered '4534 West Gate Blvd. SUITE 110'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:33

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered 'AUSTIN'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:33

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered 'TX'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30



US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:33

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered '78745'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30

**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:33**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered 'US'	System	20 Sep 2020 18:32:50

**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:33**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	12 Oct 2020 14:17:25
User entered '4'	System	02 Oct 2020 12:31:25
User entered '3'	System	01 Oct 2020 12:09:27
User entered '2'	System	29 Sep 2020 14:49:32
User entered '1'	System	20 Sep 2020 18:32:50

**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (2)**

**Generated On: 26 Nov 2020 10:59:33**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
User entered '29/Sep/2020 10:49'	System	29 Sep 2020 14:49:32

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:59:33

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
User entered 'I'	(b) (4), (b) (6)	29 Sep 2020 14:49:32

**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:33**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'USA-US203-2020-MRNA-1273-P301000002'	System	20 Sep 2020 17:57:05

**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:33**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'Yes (Y)'	System	20 Sep 2020 17:57:05

**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:33**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'No (N)'	System	20 Sep 2020 17:57:05



**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:33**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'No (N)'	System	20 Sep 2020 17:57:05

**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:33**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'Yes (Y)'	System	20 Sep 2020 17:57:05

**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:33**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'No (N)'	System	20 Sep 2020 17:57:05

**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:33**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'No (N)'	System	20 Sep 2020 17:57:05

**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:33**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'No (N)'	System	20 Sep 2020 17:57:05

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered 'PAUL'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered 'PICKRELL'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:33

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered '4534 West Gate Blvd. SUITE 110'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30



US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:33

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered 'AUSTIN'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:33

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered 'TX'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:33

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered '78745'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30

**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:33**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered 'US'	System	20 Sep 2020 18:32:50

**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:33**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	12 Oct 2020 14:17:25
User entered '4'	System	02 Oct 2020 12:31:25
User entered '3'	System	01 Oct 2020 12:09:27
User entered '2'	System	29 Sep 2020 14:49:32
User entered '1'	System	20 Sep 2020 18:32:50

**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (3)**

**Generated On: 26 Nov 2020 10:59:33**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
User entered '01/Oct/2020 08:09'	System	01 Oct 2020 12:09:27

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 10:59:33

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:31:12
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
User entered 'I'	(b) (4), (b) (6)	01 Oct 2020 12:09:27

**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:33**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'USA-US203-2020-MRNA-1273-P301000002'	System	20 Sep 2020 17:57:05



**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:33**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'Yes (Y)'	System	20 Sep 2020 17:57:05

**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:33**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'No (N)'	System	20 Sep 2020 17:57:05

**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:33**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'No (N)'	System	20 Sep 2020 17:57:05

**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:33**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'Yes (Y)'	System	20 Sep 2020 17:57:05

**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:33**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'No (N)'	System	20 Sep 2020 17:57:05

**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:33**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'No (N)'	System	20 Sep 2020 17:57:05

**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:33**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'No (N)'	System	20 Sep 2020 17:57:05

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered 'PAUL'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30



US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered 'PICKRELL'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:33

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered '4534 West Gate Blvd. SUITE 110'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:33

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered 'AUSTIN'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:33

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered 'TX'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:33

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered '78745'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30

**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:33**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered 'US'	System	20 Sep 2020 18:32:50

**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:33**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	12 Oct 2020 14:17:25
User entered '4'	System	02 Oct 2020 12:31:25
User entered '3'	System	01 Oct 2020 12:09:27
User entered '2'	System	29 Sep 2020 14:49:32
User entered '1'	System	20 Sep 2020 18:32:50

**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (4)**

**Generated On: 26 Nov 2020 10:59:33**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '02/Oct/2020 12:31'	System	02 Oct 2020 12:31:25



US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 10:59:33

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:17:12
User entered 'I'	(b) (4), (b) (6)	02 Oct 2020 12:31:25

**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:33**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'USA-US203-2020-MRNA-1273-P301000002'	System	20 Sep 2020 17:57:05

**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:33**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'Yes (Y)'	System	20 Sep 2020 17:57:05

**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:33**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'No (N)'	System	20 Sep 2020 17:57:05

**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:33**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'No (N)'	System	20 Sep 2020 17:57:05

**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:33**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'Yes (Y)'	System	20 Sep 2020 17:57:05

**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:33**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'No (N)'	System	20 Sep 2020 17:57:05

**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:33**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'No (N)'	System	20 Sep 2020 17:57:05



**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:33**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:32:43
User entered 'No (N)'	System	20 Sep 2020 17:57:05

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered 'PAUL'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered 'PICKRELL'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:33

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered '4534 West Gate Blvd. SUITE 110'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:33

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered 'AUSTIN'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:33

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered 'TX'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:33

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	01 Oct 2020 12:09:18
Un-reviewed for Safety.	System	29 Sep 2020 14:49:32
User entered empty.	System	29 Sep 2020 14:49:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered '78745'	Eileen Euperio (b) (4)	28 Sep 2020 23:30:30

**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:33**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:22:52
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 14:49:22
User entered 'US'	System	20 Sep 2020 18:32:50



**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:33**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	12 Oct 2020 14:17:25
User entered '4'	System	02 Oct 2020 12:31:25
User entered '3'	System	01 Oct 2020 12:09:27
User entered '2'	System	29 Sep 2020 14:49:32
User entered '1'	System	20 Sep 2020 18:32:50

**US3342199**

**Folder: SAE USA-US203-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (5)**

**Generated On: 26 Nov 2020 10:59:33**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '12/Oct/2020 14:17'	System	12 Oct 2020 14:17:25

US3342199

Folder: SAE USA-US203-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 10:59:33

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User entered 'I'	(b) (4), (b) (6)	12 Oct 2020 14:17:25